MASTER'S THESIS

Risk Governance in the transition towards sustainability

An assessment of applied Risk Governance practices in the life cycle of bio-based plastic food packaging materials in The Netherlands.

van der A, J.G. (Hans)

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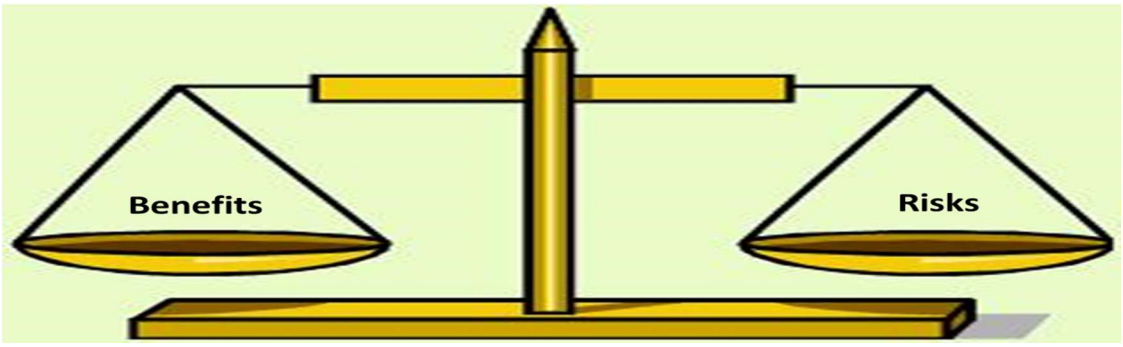

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Risicobeheer in de overgang naar duurzaamheid

Een beoordeling van toegepaste praktijken voor risicobeheersing in de levenscyclus van bio-based plastic verpakkingsmaterialen voor levensmiddelen in Nederland.

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Preface

This thesis is the result of a part-time Master study at the Faculty of Science, Department of Environmental Sciences of the Open Universiteit. This thesis is a milestone in my life time learning career. From the moment I graduated as a clinical chemical lab technician in 1980, I have been practically continuously developing myself during and alongside my daily work by following various courses. After studying computer science, food microbiology and non-profit management, I started to study environmental sciences and sustainability from 2002 onwards. I am interested in the relationships between environment, health and human behaviour. I find it very fascinating how they influence each other. Risk Governance in the transition toward sustainability is about these relationships. I have therefore done this research with great pleasure and it confirmed my believe that you need a multi-disciplinary approach to understand.

I really appreciate and thank my employer (the NVWA) for giving me the opportunity to conduct my thesis research within the organization as part of my personal development plan. This support made it possible for me to work on my research in combination with a full-time job.

This thesis was produced with the help of many people. First of all I would like to thank my supervisor and tutor Dr. Ir. Lily Fredrix for guiding my through the process of this master thesis. Thank you for your stimulating guidance and quick responses. In addition, I also want to thank my second tutor Dr. Raymond Niesink for his professional input and the review of this thesis.

Special thanks also to my mentors Prof. Dr. Dick Sijm and Dr. Dirk van Aken from the Office for Risk Assessment & Research for their professional advice, feedback and support during this research. Thanks for the educational and pleasant conversations and for keeping me on track.

Next, I am very thankful to Ing. Dita Kalsbeek-van Wijk and Lodewijk Steendam from the NVWA product safety laboratory for performing the chemical analyses and their professional contribution to the interpretation of the findings.

During this research I have had the opportunity to talk to several people involved in the life cycle of bio-based plastic food packaging materials and experts with different expertise. I am very grateful for their participation and their contributions.

Last but not least I like to thank my wife Ingeborg. Thank you for your support and your useful comments on my writing in English. Also for your tolerance and understanding as I (again) disappeared into the study for a few hours. Thank you for accepting that I didn't have time to do things together on many Sundays. I hope I can make it up to you in the coming years.

Abstract

In the transition to a sustainable society, many initiatives are taken whereby new technologies and materials are developed. Inevitably, new technologies and materials often have disadvantages that manifest themselves as risks of a completely different nature than the risks that these innovations claim to reduce. There are examples of innovations with a sustainability claim that entailed risks to public health. Throughout the lifecycle of a new product or technology, decision makers can choose to take risks for achieving sustainability goals. But there are concerns about the lack of governance mechanisms (risk governance) to tackle these risks efficiently. 100% guarantee does not exist, though the internationally accepted IRGC model for risk governance offers guidelines for early identification and treatment of risks.

In this study, the risk governance of the life cycle of bio-based plastic food (contact) packaging materials (FCM) was assessed using the IRGC model. Three of these packaging materials were assessed on their risk governance applications in all phases of their life cycle to prevent or control public health risks. In addition to the assessment of the available documents, interviews were conducted for each case with representatives of all stages in the life cycle. Based on this information the used strategies are described and an overview of the motivations and barriers has been drawn up. In a next step of the research, experts were asked to share their views on the findings and identified strategies. The strategies were then assessed for completeness, effectiveness and practical applicability. The strategies per case were also compared with the IRGC model. To get insight in the presence of potentially hazardous substances, eighteen randomly sampled bio-based FCM were analysed .

It has been established that there is no structural application of risk governance in the three bio-based FCM studied. Strategies are applied to manage public health risks, but these are usually implemented too limited to effectively manage the identified risks. It has also been established that none of the partners in the chain apply risk governance to the entire life cycle. The strategies are mainly applied to comply with the relevant legislation. Guaranteeing the stability of the product properties and the continuity of the production process complete the most important motivations for risk management. Insufficient information exchange between the stakeholders in the lifecycle due to trade secrets, lack of financial resources and lack of sense of necessity seem to be the main reasons for the limited implementation. The findings of the chemical analysis provide indications of potential health risks in most of the analysed samples. Various unauthorized substances were found.

The most important lessons and recommendations that can be drawn from this study to improve the life cycle risk management of bio-based plastic FCM are: 1) Implement risk governance principles as a structural part of business operations, 2) Use different perspectives and expertise to identify potential new risks or identify potential factors that can create or influence risks, 3) Take responsibility, involve all chain partners in advance and discuss the feasibility of the expected benefits of the product and the management of potential risks in the life cycle, and 4) Be transparent, because complete openness and sharing of honest information is essential to assess and manage risks.

The IRGC model appears to be comprehensive and labour-intensive. That is why a relatively easy-to-apply risk governance step-by-step plan, incorporating parts of the IRGC model and the principles of the PDCA management method, has been proposed for small and medium-sized companies.

This study has not investigated the safety of bio-based FCM. The focus of the research was on the applied strategies for risk governance. The conclusion that the strategies applied are too limited and the findings of potentially hazardous substances in the materials examined, does not mean immediate action must be taken or the materials examined are unsafe. Nor has a comparison been made with life cycles of other sustainable or traditional products. Therefore, no statement can be made as to whether the situation is better or worse than with other life cycles. Further research into the above aspects is recommended.

Samenvatting

In de transitie naar een duurzame samenleving worden veel initiatieven genomen waarbij nieuwe technologieën en materialen worden ontwikkeld. Onvermijdelijk hebben nieuwe technologieën en materialen ook nadelen die zich vaak manifesteren als risico's van een heel andere aard dan de risico's die deze innovaties beogen te verminderen. Er zijn voorbeelden dat innovaties gericht op duurzaamheid leiden tot risico's voor de volksgezondheid. In de gehele levenscyclus van een nieuw product of technologie kunnen de besluitvormers kiezen om risico's te nemen voor het bereiken van duurzaamheidsdoelen. Maar er zijn zorgen over het gebrek aan risicobeheer (risk governance) om deze risico's efficiënt aan te pakken. 100 % garantie bestaat niet, maar het internationaal geaccepteerde IRGC model voor risk governance biedt richtlijnen voor vroegtijdige identificatie en beheersing van risico's.

In dit onderzoek is de risk governance van de levenscyclus van bio-based plastic voedselverpakkingsmaterialen (FCM) beoordeeld met behulp van het IRGC model. Van drie van deze verpakkingsmaterialen is onderzocht in hoeverre risk governance in alle fasen van de levenscyclus is toegepast om volksgezondheidsrisico's te voorkomen of te beheersen. Naast een beoordeling van de beschikbare documenten zijn voor elke casus interviews gehouden met vertegenwoordigers van alle stadia in de levenscyclus. Op basis van deze informatie is er een overzicht gemaakt van de genoemde barrières en motivaties voor toepassing van risk governance en zijn de strategieën beschreven die worden toegepast. In een volgende stap van het onderzoek is een aantal experts gevraagd om hun visie te delen over de bevindingen en de geïdentificeerde strategieën. De strategieën zijn vervolgens beoordeeld op volledigheid, effectiviteit en praktische toepasbaarheid. Daarnaast zijn achttien willekeurige bemonsterde bio-based FCM geanalyseerd op de aanwezigheid van mogelijk gevaarlijke stoffen.

Vastgesteld is dat er bij de drie onderzochte bio-based plastic voedselverpakkingsmaterialen geen sprake is van een structurele toepassing van risk governance. Er worden wel strategieën toegepast, maar deze worden meestal te beperkt uitgevoerd om effectief de beoogde risico's te beheersen. Ook is vastgesteld dat geen van de partners in de keten risk governance toepast op de volledige levenscyclus. De strategieën worden vooral toegepast om aan de relevante wetgeving te voldoen. Daarnaast zijn het borgen van de stabiliteit van de producteigenschappen en de continuïteit van het productieproces de belangrijkste motivaties voor risicobeheersing. Onvoldoende informatie-uitwisseling tussen de schakels van de ketens vanwege bedrijfsgeheimen, gebrek aan financiële middelen en het gebrek aan gevoel van noodzaak, lijken de belangrijkste oorzaken voor de beperkte uitvoering. De bevindingen van de chemische analyse geven enkele indicaties van potentiële gezondheidsrisico's in de meeste geanalyseerde monsters. Verschillende niet-toegestane stoffen werden gevonden.

De belangrijkste lessen en aanbevelingen van deze studie om het risicobeheer in de levenscyclus van bio-based plastic FCM te verbeteren, zijn: 1) Implementeer risk governance principes als structureel onderdeel van de bedrijfsvoering, 2) Gebruik verschillende invalshoeken en expertises, om potentiële nieuwe risico's te identificeren of mogelijke factoren te identificeren die risico's kunnen creëren of beïnvloeden, 3) Neem de regie, betrek vooraf alle ketenpartners en bespreek de haalbaarheid van de verwachte voordelen van het product en het beheer van potentiële risico's in de gehele levenscyclus, en 4) Wees transparant, want volledige openheid en het delen van eerlijke informatie is essentieel om risico's te kunnen beoordelen en te beheersen.

Het IRGC model blijkt uitgebreid en arbeidsintensief. Daarom is een relatief eenvoudig toe te passen risk governance stappenplan, waarin onderdelen van het IRGC model en de principes van de PDCA management methode zijn verwerkt, voorgesteld voor kleine en middelgrote bedrijven.

Deze studie heeft niet de veiligheid van bio-based FCM onderzocht. De focus van het onderzoek lag op de toegepaste strategieën voor risk governance. De conclusie dat de toegepaste strategieën te beperkt zijn met de aanwezigheid van potentieel gevaarlijke stoffen in de onderzochte materialen, betekent niet dat onmiddellijk actie moet worden ondernomen of dat de onderzochte materialen onveilig zijn. Ook is er geen vergelijking uitgevoerd met levenscycli van andere duurzame of traditionele producten. Daarom kan geen uitspraak worden gedaan over de vraag of de situatie beter of slechter is dan bij andere levenscycli. Nader onderzoek naar bovenstaande aspecten wordt aanbevolen.

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BPA	Bisphenol A
BPAT	Polybutylene adipatecoterephthalate
BuRO	Bureau Risicobeoordeling & Onderzoek (Office for Risk Assessment & Research)
CA	Cellulose acetate
CAS	Chemical Abstracts Service
DOC	Declaration of Compliance
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPFL	École Polytechnique Fédérale Lausanne
EU	European Union
FCM	Food Contact Material
FDCA	Furanedicarboxylic acid
GFSI	Global Food Safety Initiative
GMP	Good Manufacturing Practice
IRGC	International Risk Governance Council
LDPE	Low Density Polyethylene
NIAS	Non Intentionally Added Substances
NVWA	Nederlandse Voedsel en Waren Autoriteit (The Netherlands Food and Consumer Product Safety Authority)
PBS	Polybutylene succinate
PE	Polyethylene
PEF	Polyethylene furanoate
PHA	Polyhydroxyalkanoate
PLA	Polylactic acid
PP	Polypropylene
PTT	Polytrimethylene terephthalate
QM	Maximum amount in the material
SML	Specific Migration Limit
TPA	Terephthalic acid
TPS	Thermoplastic starch

1 Introduction

1.1 Risk Governance in the transition towards sustainability

Transition towards sustainability

To meet society's long term goals and emerging challenges, like decoupling economic growth from environmental pressure, managing natural resources in a sustainable way, improving food security, reducing poverty, etc., a paradigm shift towards sustainability is essential. In other words a transition is needed from the dominant fossil based economy towards a bio-based, circular economy. This transition involves not just changes in technology but also changes in consumer practices, policies, cultural meanings, infrastructures and business models. (Johnstone & Newell, 2018; Markard, Raven, & Truffer, 2012; Morone, 2018; National Research Council, 1999). Innovations in new technologies and materials and policies supporting it are considered critical in realizing sustainability transitions, because future sustainable societies are difficult to imagine without radical technological change and new materials (van der Jagt, Raven, Dorst, & Runhaar, 2019).

Risk migration

Unavoidably, new technologies and materials also have disadvantages which often manifest themselves as risks of a very different nature than the risks these innovations claim to reduce. These new and emerging risks are often unforeseen and become apparent only after a new technology or consumer product has become widespread. Classic examples are for instance:

- Brominated flame retardants, which reduced the risk of fire, but turned out to be endocrine disruptors causing long term health risks (Alcock & Busby, 2006) and
- plastics, which are ideal packaging material, but turned out to cause waste accumulation in critical areas like the oceans (PSF, 2018).

This phenomenon is referred as 'risk migration' or 'risk transformation' (Busby, Alcock, & MacGillivray, 2012).

Van der Sluijs, Wardekker and Kouloumpi (2013) concluded that while many technological developments at first glance seem to contribute to sustainability, this is not always the case on the long term. They found some indications that innovations aimed at improving material efficiency or sustainability result in risks regarding human and ecological health. They also found that the potential of lessons learned from earlier studies to prevent risk migration is highly underutilized. The main reason for this is, that these lessons are not widely known and have hardly been internalized by those working at the frontiers of technological innovation. For instance, consider the introduction of the reusable polycarbonate plastic bottles. Polycarbonate contains bisphenol A (BPA), a toxic substance which can be released from the bottle into liquids. If the lessons learned had been applied within a risk governance structure, this risk would have been recognized at an earlier stage. In this example there was insufficient critical reflection of the possible risks. Van der Sluijs et al. also concluded that innovation is often driven by competition between firms in a globalized economy and has drivers that are very different from the various aims of sustainability and human health. They identified a top 10 of circumstances / characteristics that may cause risk migration (Table 1).

***Table 1**: Top 10 of circumstances /characteristics of risk migration (van der Sluijs et al., 2013).*

Rank	Circumstance / characteristic
1	Lack of systems analytical approach
2	Incomplete life cycle assessment
3	Lack of critical reflection on risks and promised benefits
4	No incentives to meet ALARA (As Low As Reasonably Achievable)
5	Persistence and/or bioaccumulation
6	Ignoring ignorance
7	Novel material / special unfamiliar properties
8	Mismatch novel aspects and authorization tests / standards etc.
9	Unreflective upscaling from small scale experiences
10	Non-standard situations

Risk governance

Many risks, and in particular those arising from emerging technologies and innovative materials and products, are accompanied by potential benefits and opportunities. Today's globalised world is characterised by increasing interconnectedness, social networking and fast-paced technological change. These characteristics have, in addition to opportunities, the potential to increase vulnerabilities and to create new risks with impacts on a large scale and sometimes over a long time span.

In the entire life cycle of a new product or technology, the decision-makers may defensibly choose to take risks to obtain the associated benefits. Indeed, risk-taking may be crucial to achieving technological innovation, economic development, sustainability and social welfare. But there are serious concerns from governments, the private sector, as well as the general public about the lack of governance mechanisms to efficiently deal with these risks; to resolve trade-offs between diverse, sometimes conflicting, needs and interests; or to deal with potential risks from new technologies in the context of global trade.

The challenge of risk governance lies in enabling societies to benefit from opportunities while minimising the negative consequences of the associated risks. By applying good risk governance, all players in the chain can make the right decisions, contribute to the responsible application of new technologies and materials and win the trust of politicians and the general public.

Risk refers to the uncertainty about and the severity of the consequences of an activity or event with respect to something that human's value. Uncertainty can pertain to the type of consequences, the likelihood of these occurring (often expressed in probabilities), the severity of the consequences or the time or location where and when these consequences may occur. **Governance** refers to the actions, processes, traditions and institutions by which authority is exercised and decisions are taken and implemented. **Risk governance** applies the principles of good governance to the identification, assessment, management and communication of risks (IRGC, 2017).

The international Risk Governance Council (IRGC)

The IRGC is an independent non-profit foundation which aims to help improve the understanding and management of risks and opportunities by providing insight into systemic risks that have impacts on human health and safety, on the environment, on the economy and on society at large. Started as a governmental platform, IRGC relies nowadays entirely upon funding and research contributions from its network members and grant-making institutions, both private and public.

IRGC was formally founded in Geneva as a private foundation in 2003. The Swiss government financially supported IRGC as a multi-stakeholder and neutral convening platform for policy makers, scientists and the private sector to discuss the challenges of risk governance. In June 2012, the IRGC secretariat moved its offices from Geneva to the campus of the École Polytechnique Fédérale (EPFL) in Lausanne, Switzerland. From January 2016, IRGC collaborates with EPFL, with which it organises its activities (IRGC, 2019).

IRGC develops concepts and tools for evidence-based risk governance. The Risk Governance Framework was developed for IRGC by a team of risk experts chaired by Prof. Ortwin Renn. In 2005 a first detailed description of the framework was published. Based on this work and on feedback from practical applications in 2017 a revised version was published (IRGC, 2017).

IRGC Framework

The IRGC Framework provides guidance for early identification and handling of risks, involving multiple stakeholders. It recommends an inclusive approach to frame, assess, evaluate, manage and communicate important risk issues, often marked by complexity, uncertainty and ambiguity. The Framework is generic and adaptable. It can be tailored to various risks and organisations.

In figure 1 a detailed representation of the IRGC framework is shown. In general the framework is a continuous process and comprises four interlinked elements and three cross-cutting aspects:

1. Pre-assessment – Identification and framing.

This element leads to framing the risk, early warning, and preparations for handling it. It involves relevant actors and stakeholder groups, so as to capture the various perspectives on the risk, its associated opportunities, and potential strategies for addressing it.

2. Appraisal – Assessing the technical and perceived causes and consequences of the risk.

This element develops and synthesises the knowledge base for the decision on whether or not a risk should be taken and/or managed. If so, then it identifies and selects what options may be available for preventing, mitigating, adapting to or sharing the risk.

3. Characterisation and evaluation – Making a judgment about the risk and the need to manage it.

Next is the process of comparing the outcome of risk appraisal (risk and concern assessment) with specific criteria. Determine the significance and acceptability of the risk(s), and prepares decisions.

4. Management – Deciding on and implementing risk management options.

Last element in this cycle leads to the design and implementation of the actions and remedies required to avoid, reduce, transfer or retain the risks.

The cross-cutting aspects are: Communicating (transparent and inclusive), engaging with stakeholders (for assessing and managing risks) and considering the (social) context.

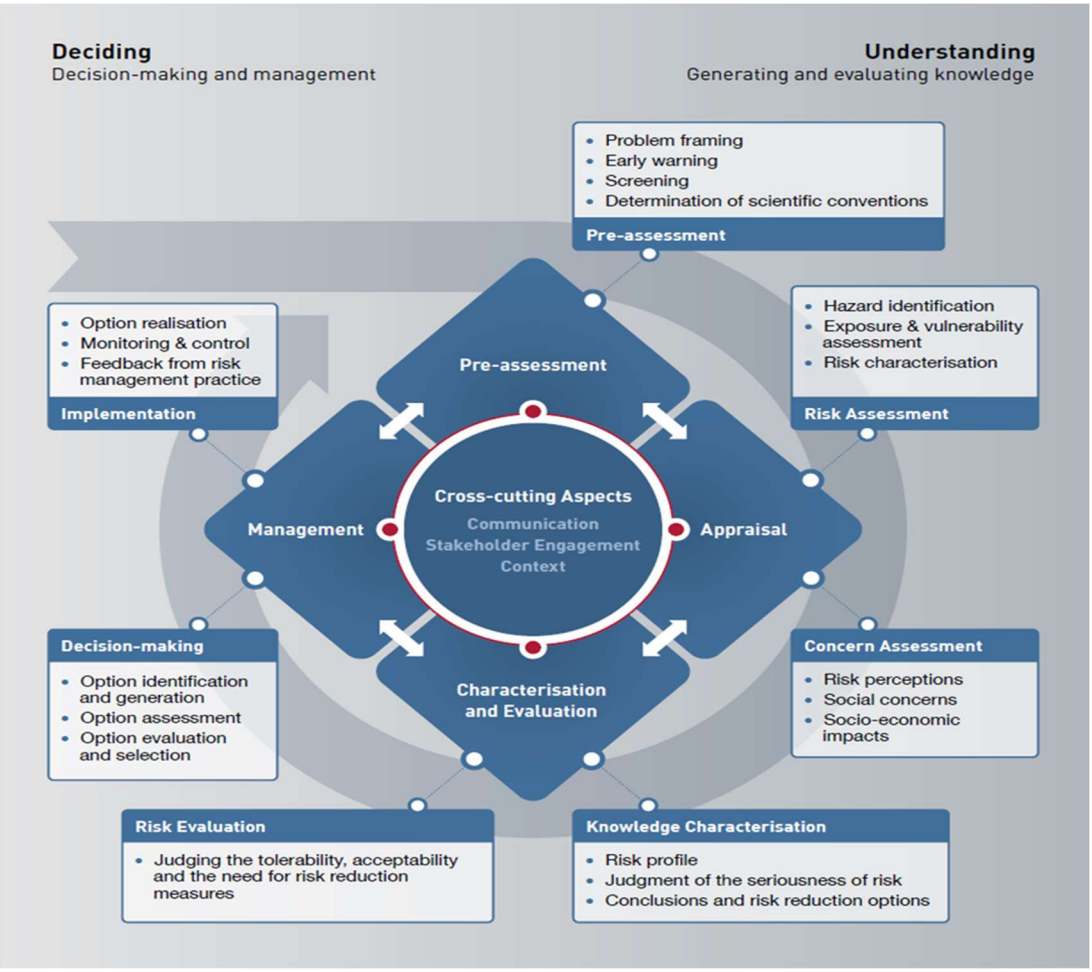

***Figure 1**: Detailed visual representation of the IRGC Risk Governance Framework. Reprinted from " Introduction to the IRGC Risk Governance Framework, revised version", by the International Risk Governance Council, 2017, p.10.*

Joint responsibility

Developers, producers, retailers, government and consumers have an interest in the promises, but also in the safety of innovative products and technologies. Developers and producers have a duty to make and deliver a product that is safe. The various examples that were mentioned earlier, show that compliance with legislation does not always guarantee safety. Producers can therefore be expected to perform additional risk analysis. The government has multiple roles, for example as policymaker, risk assessor and supervisor. The consumer or organisations acting on behalf of consumers influence the supply and potential market of innovative products. They largely determine the social debate by expressing opinions and value judgments. Further, as potential role, consumers could base their consumption behaviour more on ethical grounds. They should take responsibility; ask difficult questions to the producers; say no when appropriate and in case they observe undesirable side effects they should report those to the producer and to the authorities. They are also the users who must be able to deal responsibly with innovative products. They must have sufficient information and knowledge, so that possible risks that may arise from misuse are prevented.

The application of the Risk Governance Strategy in the entire life cycle from development to waste processing seems to be a good addition to prevent and/or manage risk migration. Especially in the early stages of the development and introduction process of new sustainable materials. Unfortunately, this strategy does not seem to be commonly used in this sector. Promotion and further elaboration to make it practically usable in this sector is recommended (van der Sluijs, Wardekker & Kouloumpi, 2013).

The life cycle of bio-based plastic food packaging materials as a study object

A good example within the transition towards sustainability is the search for sustainable alternatives for fossil based plastic. The search for alternatives for traditional plastic food packaging is booming, and lots of promising bio-based and biodegradable plastics innovations are developed (Muller, González-Martínez, & Chiralt, 2017; Oever, Molenveld, Zee, & Bos, 2017). In the development and the marketing of these new products the main focus aims to be on reducing the environmental burden. The innovation is judged to be successful if it contributes to the reduction of the amount of plastic that might end up in the environment. The attention in the introduction and marketing of this alternative is therefore mainly about this benefit. Important questions, however are: ***What about the disadvantages and possible risk migration to public health? Are those thoroughly known, assessed, managed and communicated?***

Recently a review of evidence relating to potential risks and other unintended consequences of replacing fossil based plastic food contact materials (FCM) with bio-based materials was reported (Bonwick, Bradley , Lock, & Romero, 2019). One of their main findings was that limited research into the development of bio-based FCMs derived from agri-food by-products, and the associated risks to the consumer, has been undertaken. Information on the presence of contaminants such as heavy metals, persistent organic contaminants and natural toxins is required. Very limited information is also available on the allergenicity of bio-based FCMs as well as the potential for transfer of allergens to food.

Based on the knowledge and circumstances described above, the life cycle of bio-based food packaging materials is chosen as a study object. It is a good representative of technical innovations in the transition to sustainability, where risk governance seems to be necessary to prevent and/or manage risk migration because it meets the following principles: 1) new technologies are used, 2) new materials are developed, 3) multiple stakeholders, each with their own interests and motives, are involved and 4) the relatively high risk to public health because the materials come into contact with food.

1.2 Problem description

Need for reducing food waste by appropriate packaging

Estimates foresee that the global population reaches 9.6 billon people in the year 2050. A growing population and consumption means that the global demand for food will increase for at least another 30 years. This, accompanied with an increasing competition for land, water, and energy, in addition to overexploitation of land and shortage of minerals, will affect our ability to produce enough food.

This contributes to the urgency to reduce the impact of the food system on the environment. A multifaceted and linked global strategy is needed to ensure sustainable and equitable food security (Godfray et al., 2010).

The United Nations (UN) promote Sustainable Development. On September 25th 2015, 193 world leaders committed to reach 17 goals to promote prosperity while protecting the planet. Goal number 14 focusses on responsible consumption and production. Reducing food waste is one of the actions that must be undertaken to reach this goal (FAO, 2011; UN, 2015, 2019).

One of the global strategies in reducing food waste is by appropriate packaging. Inappropriate packaging is responsible for a high degree of waste, when they insufficiently protect food from preservation, physical damage, soiling and microbiological spoilage. Especially in developing countries where suitable technologies and materials are often scarce, inappropriate packaging commonly exacerbates food shortages (Quested, Parry, Easteal, & Swannell, 2011).

Concerns about the increasing use of plastic as food packaging material

Materials such as glass, metals, paper and paperboard and plastics have traditionally been used in food packaging. Plastic materials include a wide variety ranging from rigid to flexible forms. Often, several materials are combined to exploit each material's functional or aesthetic properties. The use of plastics in food packaging has continued to increase. This is due to the low cost of these materials and their functional advantages (such as thermoseal ability, microwave ability, optical properties and unlimited sizes and shapes) over traditional materials such as glass and tinplate (Geueke, Groh, & Muncke, 2018; Marsh & Bugusu, 2007; Muncke et al., 2017; Trinetta, 2016).

The worldwide annual production of plastics (almost 350 million tons in total in 2017) shows a slight increasing trend for the last years. In figure 2 the distribution of the global plastic production is shown. China is the largest producer of plastics (29,4%), followed by Europe (18,5%). In Europe, the packaging industry is the largest user of plastic. It represents 40% of the total plastic demand (PlasticsEurope, 2018).

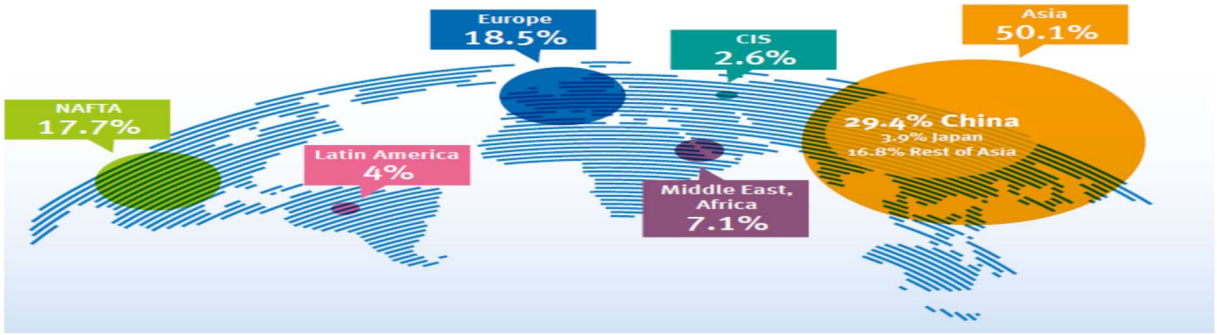

Figure 2: *Distribution of the global plastics production in 2018. Reprinted from "Plastics-The Facts 2018. An Analysis of European Plastics Production, Demand and Waste Data", by PlasticsEurope, 2018, p19.*

Plastics packaging brings many societal benefits and offers future technological advances in appropriate food packaging and reduces food waste. However, the current production process and usage throughout the lifecycle is not sustainable. Most of the plastic packaging, is fossil-based, is single use and is rapidly discarded. Plastic packaging causes severe ecological problems because plastic is almost indestructible; it takes hundreds of years for it to break down and represents high recycling costs. Concerns about usage and disposal are diverse and include large amounts of non-degradable plastic waste accumulation in critical areas on different places all over the world. Also the leaching of chemicals, such as brominated flame retardants, plasticisers, metals, dyes, etc., from plastic products into food and water is reason for concern as this leads to transfer of chemicals to wildlife and humans (Boon, te Biesebeek, Brants, Bouwmeester, & Hessel, 2018; CPB, 2017; Geueke et al., 2018; Nerin et al., 2018; Pomatto et al., 2018; PSF, 2018; Thompson, Moore, vom Saal, & Swan, 2009).

The future of the plastic economy

Despite the many benefits, the current plastics packaging economy has negative aspects that are becoming more apparent due to the still increasing production quantities. For example; after a short first use cycle, 95% of plastic packaging material value is lost to the economy and a staggering 32% of plastic packaging escapes collection systems, with a huge risk of burdening the environment (EllenMacArthurFoundation, 2017). To move the plastics value chain into a positive spiral of value capture, stronger economics and better environmental outcomes, the Ellen McArthur Foundation has outlined in a model what "the new plastic economy" should look like. This model (figure 3) is widely accepted and policy is formulated by governments and the business communities. The three most important elements of "the new plastic economy" are:

1) Create an effective after-use plastics economy by improving the economics and uptake of recycling, reuse and controlled biodegradation for targeted applications.
2) Drastically reduce leakage of plastics into natural systems (in particular the ocean) and other negative externalities.
3) Decouple plastics from fossil feedstocks by, in addition to reducing cycle losses and dematerialising, exploring and adopting renewably sourced feedstocks.

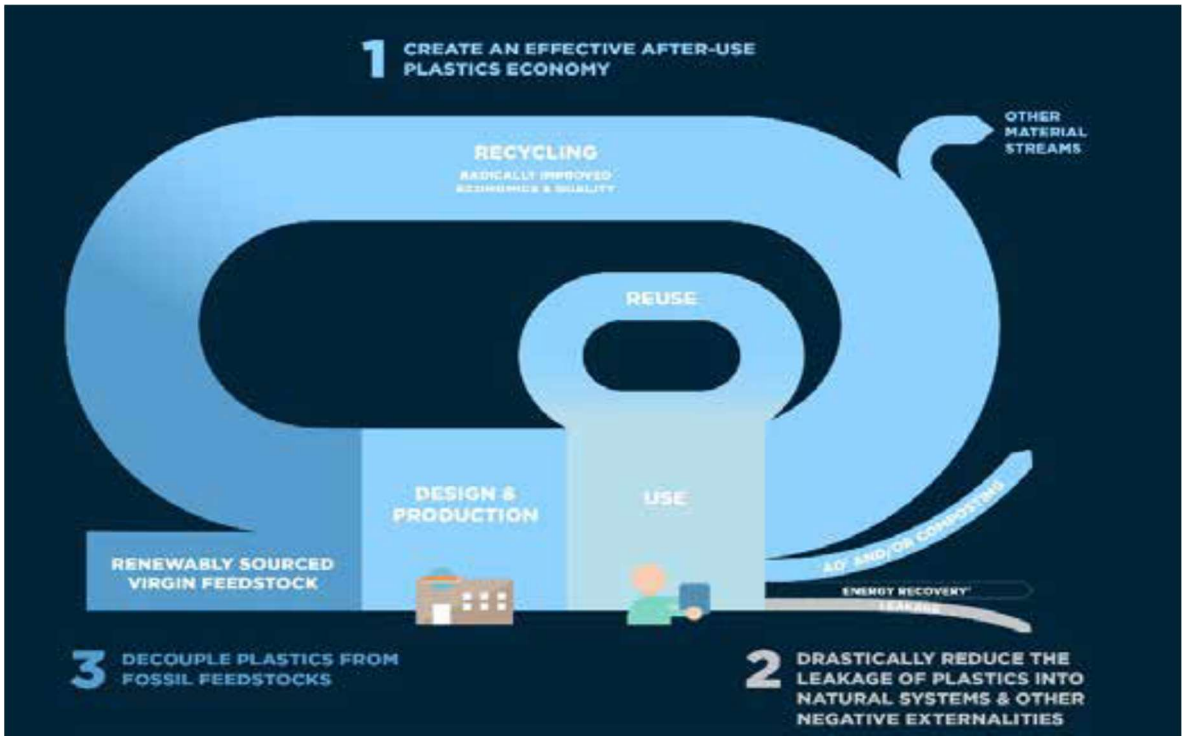

***Figure 3**: The new plastic economy. Reprinted from " The new plastics economy: Rethinking the future of plastics & catalysing action" by the EllenMacArthurFoundation, 2017, p21.*

Development and production forecast of sustainable alternatives for fossil-based plastic

To give substance to the third element of the new plastic economy there is a need to develop innovative materials and technologies for food packaging. Packaging that guarantees safety and maintains food quality for longer periods of time, with less negative impact on the environment than the currently used fossil-based and non-degradable plastics. To respond to these challenges, food packaging technology is continuously evolving. The search for alternatives for traditional plastic food packaging is booming, and lots of promising bio-based and biodegradable plastics innovations are developed (Muller et al., 2017; van den Oever et al., 2017).

> **Bio-based** is defined in European standard EN 16575 as 'derived from biomass'. Therefore, a bio-based product is a product wholly or partly derived from biomass. Biomass is material of biological origin, excluding material embedded in geological formations and/or fossilized (CEN, 2014).

According to the strategy document from the Road to Bio consortium (Panchaksharam et al., 2019) these alternatives can be divided in three groups:

1) Bio-based drop-in chemicals: these are bio-based versions of existing petrochemicals which have established markets. They are chemically identical to existing fossil-based chemicals
2) Bio-based smart drop-in chemicals: these are a special sub-group of drop-in chemicals. They are also chemically identical to existing chemicals based on fossil hydrocarbons, but their bio-based pathways provide advantages[1] compared to the conventional pathways.
3) Dedicated bio-based chemicals: these are chemicals which are produced via a dedicated pathway and do not have an identical fossil-based counterpart.

The different bio-based polymer groups are subject to different market dynamics. While the drop-ins have direct petrochemical counterparts and can substitute them, the dedicated ones have new properties and functionalities that petro chemistry does not provide. Both have their own advantages and disadvantages from a production and market perspective (Carus, Dammer, Puente, Raschka, & Arendt, 2017).

The global production capacity for bio-based building blocks for plastic is estimated to increase from 2.1 million tonnes in 2018 to approximately 3.0 million tonnes in 2023 (figure 4). In 2018 the total production volume reached 2% of the production volume of petrochemical polymers.

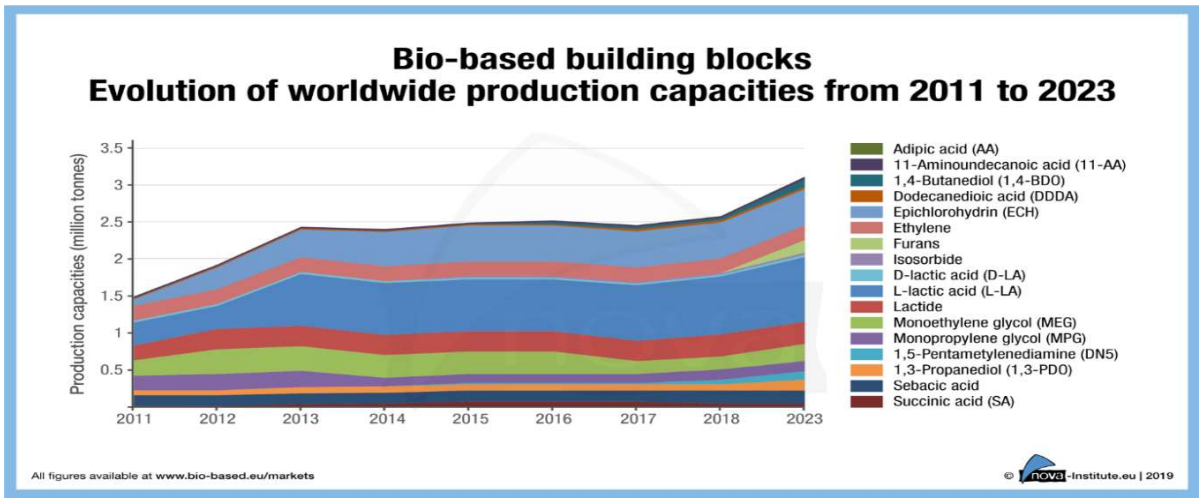

Figure 4: *Evolution of the worldwide production capacity of bio-based building blocks. Reprinted from "Bio-based Building Blocks and Polymers: Global Capacities, Production and Trends 2018 – 2023", by Chinthapalli et al., 2019, p. 8.*

[1] The Biomass Utilization Efficiency from feedstock to product is significantly higher, the production requires significantly less energy, the time-to-product is shorter due to shorter and less complex production pathways and/or less toxic or harsh chemicals are used or occur as by-products during their production process compared to the fossil-based counterpart or other drop-ins.

The increase in production capacity is mainly based on the expansion of the polylactic acid (PLA) production in Thailand, the polytrimethylene terephthalate (PTT) and starch blends in the USA. Especially PLA and starch blends will continue to grow significantly until 2023. Also new capacities of bio-based polyamides, polyethylene (PE) and, for the first time, polypropylene (PP) and poly-butyleneadipatecoterephthalate (PBAT) have been announced and some are already at an advanced stage of development. The great hopeful prospect polyethylene furanoate (PEF) will presumably only be able to offer commercial capacities after 2023 (Chinthapalli et al., 2019).

Bio-based and biodegradable plastic food packaging materials

Based on their historical development, bio-based and biodegradable plastic used for food packaging materials are divided in three generations. The first generation of bio-based packaging materials were used for shopping bags and consisted of synthetic polymers such as low-density polyethylene (LDPE) with 5–15% starch fillers and pro-oxidative and auto-oxidative additives. Although these materials disintegrated or bio-fragmented into smaller molecules when composted, they did not biodegrade. This gave a very poor image to biodegradable products, leading to public outrage with many consumers feeling that they had been misled by the biodegradability claims. The second-generation materials consist of a mixture of gelatinised starch (40–75%) and LDPE with the addition of hydrophilic copolymers such as ethylene acrylic acid, poly-vinyl alcohol and vinyl acetate which act as compatibility agents. Complete degradation of the starch takes 40 days and degradation of the entire film a minimum of 2–3 years. Third-generation materials consist of almost completely bio-based materials and are biodegradable.

Biodegradability is defined in the EU standard 13432:2000 as a measure of the actual metabolic, microbial conversion, under composting conditions, of the packaging sample into water, carbon dioxide and new cell biomass. Within a maximum of 6 months, biodegradation of the test sample must generate an amount of carbon dioxide that is at least 90 % as much as the carbon dioxide given off from the control / reference material.

In addition to a classification based on alternative applications for fossil plastics as described by Panchaksharam et al. (2019), in their Road to Bio report, these third-generation plastics can also be classified into three main categories according to their origin and method of production (Bradley, 2010; Petersen et al., 1999; Robertson, 2008).

Category 1: Polymers directly extracted/removed from biomass. Examples are polysaccharides such as starch and cellulose and proteins like casein and gluten.

Category 2: Polymers produced by classical chemical synthesis using renewable bio-based monomers. Several types of conventional plastics can be synthesised using bio-based monomers in place of the usual fossil-based sources. The finished plastics are indistinguishable from the fossil-based versions. Good example are bio-polyethylene and bio-polyethylene terephthalate. Also PLA, a bio-polyester polymerized from lactic acid monomers falls into this category. The monomers themselves may be produced via fermentation of carbohydrate feedstock.

Category 3: Polymers produced by microorganisms or genetically modified bacteria. To date, this group of bio-based polymers consists mainly of the polyhydroxyalkonoates, but developments with bacterial cellulose are in progress.

The three categories are presented in schematic form in figure 5.

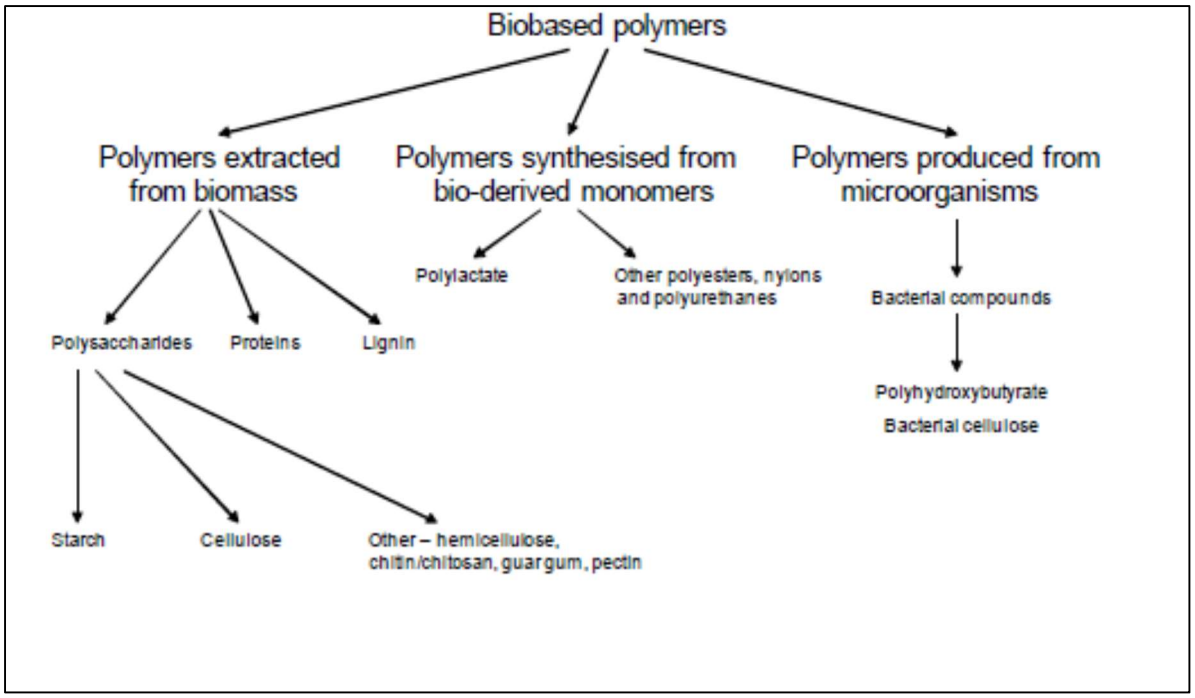

Figure 5. *The three main categories bio-based polymers. Reprinted from " Bio-based materials used in food contact applications: an assessment of the migration potential´ by Bradley, E.L., 2010, p. 63.*

Currently around 98% of all plastic food packaging is of petrochemical origin. The small share of bio-based packaging is very diverse in nature. Table 2 shows which bio-based plastics (blends) alternatives are on the market in 2018 for the most used petrochemical plastics in food packaging. This overview is not complete but it can be used as an indication. There is a wide range of plastics and this is true for both fossil-based plastics and bio-based plastics. A suitable packaging will have to be selected for each type of food with its properties. A careful selection of the appropriate packaging material in relation to the food content is also very important to ensure food safety.

Table 2*: Overview of packaging applications for petrochemical plastics and the bio-based alternatives*

Petrochemical plastic	Application	Bio-based alternative
PE (Polyethylene)	Films, bags and bottles	Starch blends Bio-PE PLA (Polylactic acid) PHA (Polyhydroxyalkanoate) blends
PP (Polypropylene)	Films, bottles and thermoformed products	Bio-PBS (Polybutylene succinate) PLA and PLA blends PHA (Polyhydroxyalkanoate) blends Bio-PP *in development*
PET (Polyethylene terephthalate)	Bottles, trays, blisters and cups	Bio-PET PLA PEF (Polyethylene furanoate) *in development*
PS (Polystyrene)	Hard plastic packaging (thermoformed) and foam	PLA CA (Cellulose acetate) Starch blends

Note. Adapted from " Catalogus bio-based verpakkingen" by Molenveld, K. & van den Oever, M., 2014, p.39. , and "Bio-based and biodegradable plastics : facts and figures : focus on food packaging in the Netherlands." by van den Oever. M. et al., 2017, p.33.

Bio-based plastics, such as starch blends, PLA, bio-PET and bio-PE, are mostly used in packaging applications. In the following chapters some background information is given for the most used bio-based plastics in food packaging and also the promising PEF will be discussed.

Starch-based plastics

Starch is a widely used naturally occurring bioplastic which is actually a storage polysaccharide in plants. It is composed of both linear and branched polysaccharides known as amylose and amylopectin, respectively. The ratio of these polysaccharides varies with their botanical origin and generally, native starches contain around 70-85% amylopectin and 15–30% amylose. Starch and starch blends are dedicated bio-based chemicals. Starch is a category 1 bio-based plastic, starch blends with other bio-based blends belong to the category 2 bio-based plastics. For processing of starch, flexibilizers and plasticizers such as sorbitol and glycerine are added. After addition of plasticizers and application of thermal and mechanical energy, these constituted thermoplastic starch (TPS) could be used as substitute for PS. Starch works as effective packaging material when it is modified to form films that provide adequate mechanical properties of high percentage elongation, tensile and flexural strength. Traditional extrusion, injection moulding and compression moulding can be used to process thermoplastic starch. Although it is possible to make useful products from TPS alone, extreme moisture sensitivity of starch leads to limited practical application. Therefore, the reality in commercialization of starch-based plastics involves blending of TPS with other polymers and additives. A lot of effort is put into developing biodegradable plastics based on starch and biodegradable polyester blends. Starch blends are widely used for food packaging applications in the form of wrap films, single-use foamed trays and boxes and table ware. Their relatively high water vapour permeability is an advantage for the fog-free packaging of warm foods. Not all starch blends are suitable for food contact applications. Starch plastics are usually blends and often contain additives such as compatibilizers and plasticizers. These components may migrate from the starch blend to the food and this is only permitted for a very limited extent in food contact applications (Bradley, 2010; OVAM, 2015; Reddy, Vivekanandhan, Misra, Bhatia, & Mohanty, 2013).

Polylactic acid (PLA)

PLA is a renewable, biocompatible and also biodegradable polymer and is one of the most widely used bioplastics. PLA is an aliphatic polyester produced by the polymerisation of lactic acid (2-hydroxypropionic acid). Lactic acid can be produced synthetically from hydrogen cyanide and acetaldehyde, or naturally by bacterial or fungal fermentation of carbon substrates, either pure (e.g. glucose and sucrose) or impure (e.g. starch). PLA and PLA blends are bio-based dedicated chemicals and belong to the category 2 bio-based plastics. Different micro-organisms can produce lactic acid, but for commercial applications mostly *Lactobacillus* is used. The molecular weight and yield of PLA depends on the purity of the monomer used. Therefore, purification of lactic acid during its production is very important for the production of PLA with consistent properties.

Specific benefits of PLA in packaging applications are its transparency, gloss, stiffness, printability, process ability and excellent aroma barrier. PLA is a rigid material with (mechanical) properties that are comparable with those of PS and PET. PLA can be converted to end products by a variety of plastics processing techniques including thermoforming, injection moulding, blow moulding extrusion, foaming, film extrusion and fibre extrusion. PLA is assessed and approved for food contact applications and therefore very suitable for packaging (Conn et al., 1995; FDA, 2002). PLA is frequently used in combination with other bio-based and/or biodegradable polymers to improve stiffness and strength and to reduce costs. PLA is used in (transparent) dishes and films, in particular for fresh organic products such as fruit and vegetables. Because of its air permeability, PLA is very suitable for the packaging of sliced lettuce (foil) and also bread (windows in bread bags). Without additional barrier materials PLA is not suitable for the packaging of water sensitive products that will be stored over longer periods. Because PLA has a relatively high water permeability, it has limited use in bottles. Bottle applications are not actively promoted by PLA producers. Still, PLA can be used for the production of bottles that have a very similar look and feel as PET bottles. The barrier properties of PLA (higher water permeability) are not sufficient to replace PET in long shelf life applications. Today, PLA is only used in small (< 1 litre) water bottles.

PLA has a low melting point, so is best suited for cold use up to around 40ºC. Where more heat resistance is needed such as in cutlery, or lids for coffee or soup, a crystallised form is used (cPLA). This involves adding chalk to the PLA to act as a catalyst, and then rapidly heating and cooling the PLA resin during production. The result is a product which is heat stable to 90ºC.

The applications of PLA can be widened by improving its properties. To achieve this, copolymers of lactic acid and other monomers such as derivatives of styrene, acrylate, and poly-ethylene oxide have been developed. PLA has also been formulated and associated with Nano sized fillers. Modification of PLA, copolymerization with other monomers, and PLA composites are some approaches that are being used to improve the stiffness, permeability, crystallinity, and thermal stability of PLA (Bradley, 2010; van den Oever et al., 2017; OVAM, 2015; Reddy et al., 2013).

Bio-PE and Bio-PET

Several types of conventional plastics can be synthesised using bio-based monomers in place of the usual fossil-based sources. The finished plastics are indistinguishable from the fossil-based and they are not biodegradable. Bio-PE and Bio-PET are bio-based drop in chemicals and belong to the category 2 bio-based plastics.

PE can be produced using bio-ethanol. Bio-ethanol is produced from fermentation of biomass, mostly sugar cane, sugar beet or starch crops such as corn and wheat. The bio-ethanol is then used to produce ethylene. By far the most important product made from ethylene is polyethylene, but ethylene is also used to produce other bio-based plastics like bio-PET. Bio-based PE was produced in the 1980s, but production ceased when oil prices fell. The increase in oil prices and the social discussion about sustainability and plastic soup have regenerated interest and bio-based polyethylene became commercially available in 2010. As the properties are identical to that of fossil-based PE, bio-based PE could potentially substitute in all applications (Bradley, 2010).

PET is one of the widely used polyesters for food packaging applications (mostly for single use bottles for beverages) and is obtained by polyesterification of terephthalic acid (TPA) with ethylene glycol. This reaction can be easily carried out using bio derived ethylene glycol. Bio-based ethylene glycol is produced using bio-based ethylene; bio-ethylene is oxidized to ethylene oxide, followed by its hydrolysis. The bio-based content is usual partial and depends on the relationship between the relative quantities of bio-based substances taking part in a production process. By using a specialized patented technology where bio-based p-xylene is converted from bio-based sugars into bio-based terephthalic acid a 100% Bio-PET is commercially available. Just like with PE, bio-based PET could potentially substitute fossil-based PET in all applications (OVAM, 2015; Reddy et al., 2013; Virent, 2011).

PEF (polyethylene furanoate)

In addition to the production of bio-TPA, work is also being done on replacing TPA by 2,5-furanedicarboxylic acid (FDCA) for the production of PEF. PEF is 100% bio-based, easily recyclable but not biodegradable. PEF is a bio-based dedicated chemical and belongs to the category 2 bio-based plastics. FDCA can be produced via chemical routes as well as via fermentation from sugars. Because FDCA has a different molecular structure than TPA, PEF has different properties than PET. For example, the reported barrier properties of PEF are for CO_2, water and oxygen significantly better than that of PET. PEF is also better UV stable. The potential of PEF is not only as a replacement for PET but also as a sustainable alternative to glass bottles. FDCA and PEF are not yet produced on a large scale, due to high production costs but there are various initiatives for commercializing PEF (Molenveld & Bos, 2019; Mulder & Tromp, 2018).

EU legislation food packaging materials

Because food packaging materials come into direct contact with food, sometimes for a long period of time, food safety must be guaranteed, also when new innovative products are introduced. To ensure food safety in the European Union (EU) general requirements for food contact materials (FCM) are laid down in Regulation (EC) 1935/2004. The general requirement in this regulation is that FCM must not release ingredients in quantities that can cause damage to health or that cause an unacceptable change in the composition of the food.

A substance may only be used in FCM if that application has been assessed and approved. Commissioned by the Council of Europe, the Belgian Scientific Institute for Public Health has developed a database which contains all substances known and used in FCM in the Member States (WIV-ISP, 2018).

Known to the Member States, however, does not mean all these substances are authorized. If a substance is not yet on the list of authorized substances, the producer must submit a technical dossier to the competent authority of a Member State. The competent authority shall inform the European Food Safety Authority (EFSA). The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids compiles the assessments and publishes them as opinions. The "Note for Guidance for preparation of an application" is leading in this process (Silano et al., 2008). Specific legislation has been developed for some materials. For example, there is specific legislation for plastics, for regenerated cellulose and for active and intelligent FCM.

To ensure good manufacture practice in the EU, manufacturers must meet the requirements laid down in Regulation (EC) 2023/2006. A Declaration of Compliance (DOC) is required for all food contact materials to be able to be placed on the European market. The manufacturer hereby declares that all relevant regulations have been observed during the production of the material. Table 3 provides an overview of relevant EU legislation for food contact materials (EU, 2018).

***Table 3**: Overview of relevant EU legislation.*

Legislation	Description of the subject
General	
Regulation (EC) No 178/2002	General Food Law
Regulation (EC) No 1881/2006	Setting maximum levels for certain contaminants in foodstuffs
Regulation (EC) No 1935/2004	Materials and articles intended to come into contact with food
Regulation (EC) No 2023/2006	Good Manufacturing Practice for materials and articles intended to come into contact with food
Specific	
Regulation (EC) No 10/2011	Plastic materials and articles intended to come into contact with food
Regulation (EC) No 282/2008	Recycled plastic materials and articles intended to come into contact with foods
Regulation (EC) No 450/2009	Active and intelligent materials and articles intended to come into contact with food
Directive 2007/42/EC	Materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

As mentioned earlier there is specific harmonized legislation in Europe for plastic materials and articles intended to come in contact with food, in addition to the general legislation for food contact materials. This specific legislation is laid down in Reg. (EC) No 10/2011. The scope of this regulation and the applicable definition for plastic do not make a distinction between bio-based plastics or plastic from petrochemical origin. This means that with regard to legislation there is no difference between bio-based or other plastics.

Plastic is defined in Reg. (EC) 10/2011 as a polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles.

European legislation in the field of packaging and waste is likely to change in the near future. The European Commission (EC) published a European strategy for plastics in a circular economy in January 2018. According to this strategy, all plastic packaging must be reusable or recyclable by 2030. For the time being, this creates tension with the essential requirements especially for food contact materials.

Various current packaging laws and regulations (such as for FCM and medicines) make it very difficult to comply with this new strategy and can clash with practice. As regards the use of recycled plastics in food contact applications, the objective is to prioritise high food safety standards, while also providing a clear and reliable framework for investment and innovation in circular economy solutions.

At this moment it is often better not to use recycled packaging materials for food because the composition of recycled material is still insufficiently known. With this in mind, the EC is committed to swiftly finalise the authorisation procedures for over a hundred safe recycling processes. In cooperation with the EFSA, the EC will also assess whether safe use of other recycled plastic materials could be envisaged, for instance through better characterisation of contaminants (EC, 2018).

Also the Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment will have an effect on the FCM market. This directive prescribed various measures with regard to certain single use plastic products (EU, 2019).

Further research and specific or amended regulation is thus highly needed, as is evident from a study by van der Linden (2018). This study investigated which hazardous substances have been demonstrated or can be expected in food by using recycled material for food contact materials. In terms of risks, almost 200 of those substances have been mentioned, of which 111 have been identified as dangerous. 18 hazardous substances could be traced to plastic packaging. Of these, only 3 were regulated in EU legislation. The risks of the presence of these substances is unknown, because there is uncertainty about the final concentrations in recycled material and therefore in the exposure (van der Linden, 2018).

The need for risk governance

Despite the existence of extensive legislation concerning the introduction of "new" food contact materials into the EU market, new and emerging risks for public health and the environment can arise. As mentioned before new technologies and products can have disadvantages which often manifest themselves as risks of a very different nature than foreseen and regulated in legislation. For example a common surfactant (surfynol) used in food packaging was found to be toxic for reproduction in mammals (Nerin et al., 2018). These new risks are often declared as unforeseen and apparent only after a new technology or consumer product has become widespread.

Are these risks really unforeseeable? According to van der Sluijs et al. (2013) the lessons learned from earlier studies are highly underutilized and innovation is driven by competition between firms in a globalized economy. In addition to the legal obligation to provide a technical dossier and a DOC, producers are not obliged to declare and demonstrate that they have carefully investigated the possible introduction of new risks to public health and the environment.

It is also possible that during the development and introduction of a packaging material not all toxicological effects are known. If some of these effects become known or evident later, these substances can turn into potential new and emerging risks.

1.3 Research objective and research questions

Research objective

In this study the application of risk governance in all links of the life cycle chain, from development to waste processing of three different bio-based plastic food packaging materials are investigated. Strategies that are used, besides compliance to legislation, to control risk migration are identified, compared and assessed. Lessons learned are used to indicate a best practice strategy, so that the possible new and emerging risks to public health as a result of the introduction of new sustainable material can be safeguarded and communicated.

The described problem statement and study approach leads to the following research objective:

To identify, improve and promote good practice Risk Governance strategies that are used to control risk migration in the life cycle of bio-based plastic food packaging materials.

The practical relevance of this objective can be found in the fact that the results of this study can be used by researchers and developers, producers and users of sustainable innovative food contact materials to address, avoid or reduce risks migration. Another practical relevance lies in the fact that the results of this study can be of practical use for the governments and the European Union in their role as policy maker, risk assessor and supervisor. The objective has also a theoretical relevance. The results can contribute to a critical reflection on both the validity of the promises and the possible risk of these new materials for food packaging. This reflection can lead to the development and/or improvement of risk appraisal theories and assessment procedures in the pre-market phase.

This research objective is in line with one of the assignments of the Office for Risk Assessment & Research (BuRO) of the Netherlands Food and Consumer Product Safety Authority, i.e. to signal new risks and threats to public health. It is also a follow-up on the research that was carried out in 2010 on behalf of BuRO. From a scientific perspective, an analysis has been made of technological innovations that can appear on the consumer market within ten years. New food packaging materials, like biopolymers was one of the subjects studied (VWA, 2010). The research for this thesis has therefore taken place at the office of BuRO and was supervised by BuRO staff.

Research Questions

The research objective addresses the following central research question:

Is the concept of risk governance implemented in the life cycle of new sustainable bio-based plastic food packaging materials and are the strategies that are commonly applied in this life cycle to control risk migration in relation to public health, sufficient?

To answer this central question, the following sub questions are presented:

1. *Which strategies have been applied per part of the life cycle for the three selected sustainable bio-based plastic food packaging materials?*

2. *Do these strategies include all aspects of the IRCG Risk Governance Framework?*

3. *What are the barriers to comply with the IRCG Risk Governance Framework?*

4. *Are potential chemical hazards and indications of possible health risks present in the composition of bio-based plastic FCM present in the Dutch market?*

5. *What are the strengths and weaknesses of the identified strategies?*

6. *What are the role and responsibility of the stakeholders in the lifecycle of plastic FCM, with regard to avoiding, reducing or constraining known, but also possible new and emerging risks that can appear by introducing innovative new FCM?*

7. *Which (new) lessons can be learned from these cases to help describe or develop a best practice strategy to control risk migration in the development of new sustainable FCM?*

1.4 Research framework

To contribute to fulfilling the research objective and to answer the research questions a practical approach is chosen. The research was set up as a ***hierarchical comparative case study*** (Verschuren & Doorewaard, 2016).

An important argument for choosing this form of a practical approach was the search for creating a large support base for the final proposals and recommendations from this research. An important part of the research objective was to improve the strategies that are commonly used. In order to actually realize this improvement a large support base is essential. It is desirable that all those involved do recognize, understand and therefore accept the proposals. To reinforce this effect, a holistic approach is chosen, whereby an attempt is made to obtain an integral picture. This is done by gathering qualitative information in an open way by studying documents, conducting interviews and to organize a workshop.

In addition, there was also a pragmatic argument. This research had to be conducted in accordance with the conditions set by the university. By choosing a case study approach, the research could stay within feasible proportions.

A comparative case study has been carried out. It was expected that there will be differences due to the fact that the development, production and use of the three selected materials is based on different ideologies, techniques and available time and finances. In the selection of the three materials, an attempt was made to achieve the greatest possible difference in the factors mentioned.

In summary the research consists of the following steps, see also the flowchart in figure 6. After an orientation and in-depth study of the subject through a literature study, three bio-based packaging materials have been selected for the case studies. In addition to a desk-research study, interviews were conducted for each case with representatives of all stages in the life cycle. Based on this research three separate descriptions of the strategies used and an overview of the motivations and barriers was drawn up. In the next step of the research, some experts were asked to give their opinion on the strategies used and whether they are sufficient per case. The strategies found were compared with the IRGC framework. The sufficiency of the used strategies were also verified by laboratory tests on the material for the presence of hazardous substances and potential risks. From the collected data, a strength and weakness analysis of the strategies was carried out.

Based on the information gathered, the strength and weakness analyses, the found motivations and barriers and the literature study, lessons learned and an relatively simple and more practical framework was suggested. These lessons learned, the simplified framework and the role and responsibilities within the life cycle were discussed and assessed in a workshop with representatives from all parties involved.

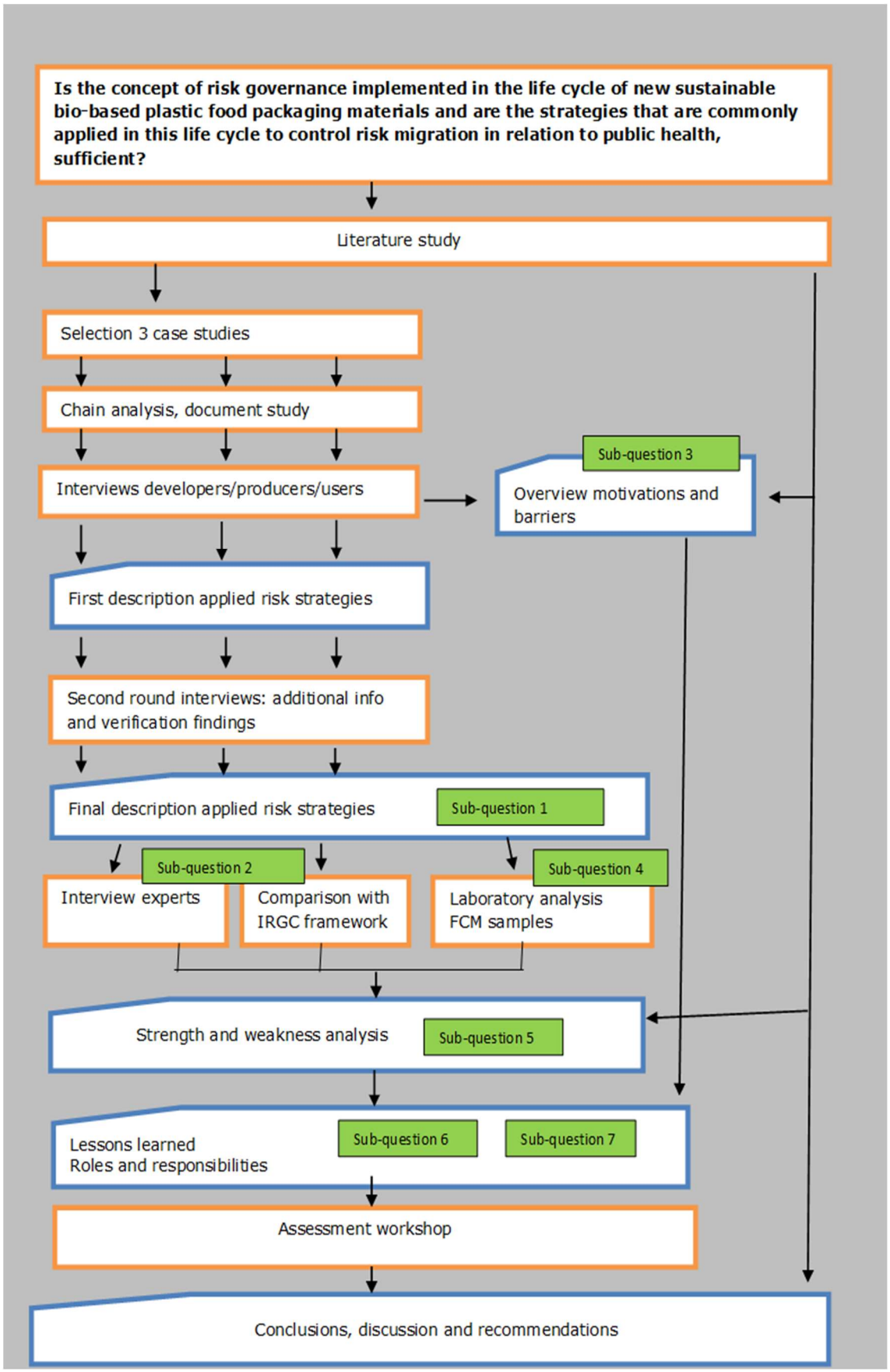

***Figure 6**: Flowchart research framework.*

2. Materials and methods

2.1 Case studies: selection and description

The scope of the research focusses on the supply of bio-based plastic food packaging materials on the Dutch market. A simple market survey was carried out by searching the internet for suppliers of bio-based food packaging materials. A combination of the following keywords: *Bio-based plastic, food packaging, Dutch market, suppliers* and *retailers* were used for searching the internet with the search engines Google[2] and Bing[3]. In addition, various supermarkets and speciality shops were visited to physically look at the products present. From this overview three bio-based plastic materials were chosen that differ as much as possible in the following aspects: the required raw materials, the chemical composition, the preparation process, the use and the disposal process. It was also preferable that the material is developed and/or produced in the Netherlands, making it within the scope of the research and which would make it probably easier to collect information from all steps in the life cycle.

The following materials have been selected:

For **case study A**, a bio-based foil for packaging of frozen products was selected. This product mainly consists of the basic polymer polyethylene. The chemical identical fossil-based version of this product already exists and has been in use for many years. To make the bio-based version, the bio-versions of the raw materials and the bio-based version of the mentioned polymer is used. The bio-polymer is supplied by one of the larger international producers. The end product is provided with a bio-based certification. The end product is produced in the Netherlands.

For **case study B**, a tray for fresh meat was chosen. The material mainly consists of PLA which was made from sugarcane. The development of this material was done by a group of Dutch and German developers. The PLA is supplied by one of the larger international producers. The end product is certified as bio-based and industrially compostable. The end product is produced in Germany.

For c**ase study C**, a material used for coffee capsules was chosen. This material is a combination of PLA and natural fibres. This material is developed in the Netherlands. The PLA is supplied by one of the larger international producers. The natural fibres are produced in licence on different places. The material used for the end product is produced in the Netherlands and in the United Kingdom. The material is bio-based and home compostable.

2.2 Data collection

Chain analyses of the life cycle

A literature review of described life cycles for bio-based plastic FCM was carried out in order to get an overview of the possible steps in the different life cycles. This review was used to create the flowchart, shown in figure 7, representing the different stages in the life cycle.

After selecting the three food contact materials, information was collected about the raw materials used, the production processes, the composition of the end product, the purpose of use and the disposal process. This information was obtained by studying documents made available by the producer or supplier and the information from the interviews with representatives from the various stages in the life cycle of the selected materials. Secondly, if available, the technical files were searched for identified risks and control measures in all stages of the life cycle.

[2] https://www.google.com/

[3] https://www.bing.com/

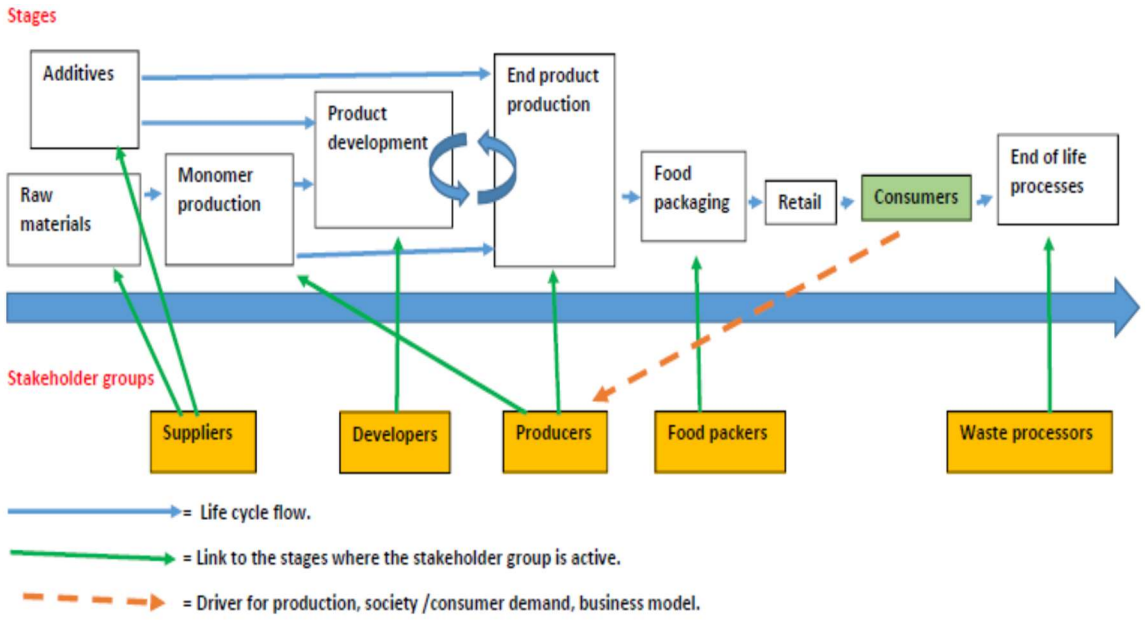

***Figure 7**: Stages and stakeholders in the life cycle of bio-based plastic food packaging materials.*

Interviews

Representatives of the stakeholder groups in the life cycle

To gain insight into what is being done to identify and prevent potential risks, what barriers are experienced and where the responsibilities are laid down in the chain, representatives from the established stakeholders groups in the life cycle of the three case studies were approached for an interview. Results of the interviews are presented anonymously, as has been agreed in advance with the interviewees. The interviews were conducted according to a fixed structure, according to the framework as included in the **appendix I.**

Eight persons were interviewed representing all stakeholder groups in the study cases. Often one person represented multiple stakeholder groups within a case study. Some interviewed persons were representative of a stakeholder group that applied to all three case studies, such as the supplier of raw materials and the waste processor. Table 4 provides an overview of the interviews conducted per case study.

***Table 4.** Number of interviews held per stakeholder group per case study.*

Stakeholder group	Case study A	Case study B	Caste study C
Suppliers	2	2	3
Developers	1	1	1
Producers	1	1	1*
Food packers	1	1	0**
Waste processors	1	1	1

*= End product was not yet in production.
**= End product was not yet available for the market

Experts

In order to assess whether the chosen strategy per selected material is sufficient to identify and manage possible risks, experts were consulted. First, the experts who also participated in the Risk Governance research that was carried out in 2010 (VWA, 2010), have been asked to contribute. These are supplemented with experts who have recently done research on bio-based plastics as food contact material. The selected experts were asked for their opinion through in depth interviews regarding the possible risks of the selected materials, and bio-plastics in general, for public health. Also their opinion was asked about the completeness and effectiveness of the used risk governance strategies in the case studies.

In depth interviews were held with nine experts from various organizations (Wageningen University and Research, CE Delft, Amsterdam University of Applied Sciences, the Netherlands Organisation for applied scientific research TNO and the NVWA). The consulted experts were specialists on one or more of the following topics: FCM legislation, FCM approval procedures, toxicology, chemistry, application and development of bio-based products, circular economy, sustainable packaging, Life Cycle Assessments (LCA) and waste processing.

Chemical analysis

The objective of the chemical analyses was to determine whether there are possible indications for (health)risks. Eighteen different bio-based plastic FCM available on the Dutch market were randomly sampled. The investigation consisted of performing a screening for the presence of Non-intentionally added substances (NIAS) and an analysis for the presence of metals in the sampled materials. The results are qualitative, the presence of the substances has been demonstrated, the concentration of the substance in the samples was not determined.

The chemical analyses were performed at the NVWA laboratory for product safety, located at Paterswoldseweg 1, 9726 BA Groningen.

Description of the applied method for screening for NIAS with GC-MS:

The preparation of the samples was done in the following manner: Cut a portion of the material into small pieces. Weigh approximately 300 mg in a glass tube. Add 1.5 ml acetone followed by 100 µl IS[4] solution of 10 µg /ml dodecane in hexane. Ultrasonic treatment for 30 minutes, filtering and transferring into a vial. 1µl of the prepared sample was under split less conditions injected into a gas chromatographic system (Agilent Technologies 7890B) and analysed with mass selective detection (Agilent Technologies 5977A). The mass range was set with a start limit of 29, the end limit was 450, a threshold of 150 was used. The chromatogram was investigated for available components by comparing the spectra with library spectra. The method used for the GC-MS analysis is described in the NVWA standard operation procedure CHE01-ND816 v7: *Identification and quantification of components in different matrices using GC-MS (NVWA, 2016).*

Only a screening has been performed, the found substances are not confirmed. Therefore the results must be used as indicative.

Description of the applied method for the analysis of the presence of metals with ICP-MS:

The preparation of the samples was done by destruction of 0.1 gram in 5 ml of HNO_3, 1 ml of H_2O_2 and 2 ml of double distilled water using a microwave. 4 ml of a prepared sample was analysed using Inductively Coupled Plasma in combination with mass selective detection (MSD) system (Perkin Elmer Nexion 2000). Step 1: in 4 minutes from 20 ℃ to 200 ℃. Step 2: 8 minutes at 200 ℃. The method used for the ICP-MS analysis is described in the NVWA standard operation procedure CHE01-WV408 v5: *Determination of elements in simulant after migration from articles intended to come in contact with food using ICP-MS (NVWA, 2018).*

[4] Internal standard

Assessment workshop stakeholders

A workshop was organized to present and verify the initial findings. Another important objective was to obtain additional information from open discussions and initiating possible "cross-contamination" between different angles and perspectives. All the persons interviewed for this study were invited, supplemented by the supervisors of the Open University and BuRO. Thirteen persons participated in the workshop. All stages in the lifecycle were represented, supplemented by a few experts from the government and the research community. After a brief plenary presentation of the findings, the attendees were divided in two groups and asked to work out a fictional case. The results of the group discussion were presented in a plenary session in which various insights and opinions were further shared in an open discussion. Propositions were presented in the last part of the workshop, to which a response was requested.

2.3 Data analysis

Identification of used risk strategies, motivations and barriers

The collected information from the interviews with the representatives of the different stages in the life cycle was assessed to find: 1) the risk identification and control strategies mentioned, 2) the motivations for these strategies mentioned and 3) the experienced barriers. These topics were arranged by the number of times they have been mentioned, who applied them and for which purpose. Which risks do they want to control?

Comparison with the IRGC Risk Governance framework

For each case a comparative judgement (meet, meets partially or does not meet) was made based on the answers and statements given to the prepared interview questions. The statements were compared with relevant subjects of the five elements of the IRGC framework. Based on the judgement results a semi quantitative score was given per element. Based on these scores, percentages are calculated to which extent the principles of the five elements of the IRGC framework are met.

Chemical analysis

The results of the chemical analysis of the sampled materials were assessed for indications for possible (health)risks. First it was examined whether the identified substances were mentioned on the positive list of the EU regulation 10/2011. In addition, the identified substances were assessed for potential hazards to public health by looking at the properties of the substances in the European Chemicals Agency (ECHA) database of registered substances[5]. If a substance is not authorized as FCM or/and if hazardous properties are known, there is an indication of a possible public health risk. In order to determine whether there is actually a risk, further research is needed with regard to concentration and migration properties.

Strengths and weaknesses analysis

Based on the information gathered from the three case studies, the strengths and weaknesses of the applied strategies were examined. The objective of this analysis is to assess the suitability of the identified strategies as elements of a best practice. To be able to assess this, the completeness, effectiveness and applicability were investigated. For the assessment of completeness, it was examined whether all aspects of concern were covered. For the assessment of effectiveness, it was examined whether the strategy actually works. To assess the applicability the complexity of the strategy, the partners involved in the chain, the technical possibilities and the costs were considered. Based on this assessment a suitability score is awarded to each strategy.

Responsibilities

The opinions of the participants about the responsibilities of the various stakeholders in the chain have been collected. It has been determined for each stakeholder how they themselves take responsibility and what is expected of them by the other partners in the chain.

[5] https://echa.europa.eu/nl/information-on-chemicals/cl-inventory-database

3. Results

All three case studies were elaborated on the basis of the information obtained from the documents received and the interviews/discussions with different stakeholders involved in the life cycle. See **Appendix II** for a detailed description per case. The results and the source of the information used for each sub research question are described in the chapters below.

3.1 identified strategies

Identified strategies for risk identification

Based on the information obtained from the interviews and the received documents, a true risk identification strategy could not be traced in all three cases. Risk identification was done on the basis of generally known risks from their professional field. The risk identification and assessment is not a structural part of the management activities. There was no overview of the identified risks available in all three cases. The risks that were mentioned are very generally defined. The following six groups of risks have been identified:

- Presence of hazardous substances in the end product.
- Continuity in production and quality.
- Migration of hazardous substances to the food to be packaged.
- Unsafe food due to inadequate packaging.
- Change in the properties of the packaged food product
- Disruption of waste flows

Because risks were only mentioned in a general sense, the actual factors that determine the risks seem to be unknown. No active research activities, from various angles, to identify potential new risks or identify possible factors that could create or influence risks were found. There was no register available describing the risk identification activities from the beginning to the present times.

Specified risk identifications like: 1) **which** hazardous substances may be present in the raw materials or in the end product that need special attention? Or 2) **which** property is essential for the food packer to be sure that the food is not spoiled? Or 3) **which** component in the formula gives the highest risk of change in properties of the packaged product? could not be answered by the interviewed persons.

Identified strategies for risk management

From the findings of the interviews held with the stakeholders of the three cases, nineteen different risk management strategies have been identified. Following the general risk identification, it appears that the applied risk management strategies also have a very general character. It has been established that risk strategies are indeed being applied, but that these are usually not fully implemented. Depending on the information available and the financial resources, choices are made. There are some differences between the three cases, particularly in the development, use and waste phase, but in general they show many similarities in the approach.

In most cases the interviewed stakeholder seem to be satisfied quickly and they do not ask further questions or specific information from their supplier. For example, with the certificate of the raw materials one is satisfied with the purity content. While a good risk assessment requires information about the complete composition of the raw materials.

Another example is the declaration by the producer of the end product that the packaging complies with the law, but he does not provide complete information about the composition of the end product because he sees this as trade secret. Both examples show that due to incomplete information sharing a "black hole" can arise in the risk inventory. The longer the chain in the life cycle, the larger this gap will be.

The costs are also an important factor in the implementation of the strategies. Companies look for a balance between the necessary activities and the desirable ones. An example of this is the frequency of the end product check. You can do this every batch or only once at the first introduction. The choice of the quantity and quality of the research methods and the performing laboratories are also often cost dependent.

The most important starting point for risk management in all three products was the fact that the end product has to comply with legislation. It is assumed that by complying with legislation the product is safe. Therefore the respondents secure that they only applied substances that were registered on a positive list for use in contact with food. Also in all the three cases the required migration tests were performed and the end product was tested for composition.

A second principle was the guarantee of continuity and quality. To be commercially successful, the FCM must be of constant quality and sufficiently available. The producer in all three cases studied tried to work with permanent partners with agreements on delivery and confidentiality. Different constructions were used but the aim is to put the product on the market with a group of reliable partners where all partners must take their responsibility. Also in the production stage strategies are applied to ensure quality and prevent production errors.

In the packaging stage, the food packer applies various strategies to ensure proper use of the packaging and to ensure that the food remains safe until the expiry date. Physical checks and shelf life studies are performed.

Last but not least, strategies have been identified to ensure that the use of the material and the waste flows take place correctly. These strategies consist of information activities for consumers, but also by contributing to waste collection facilities.

Comparison with the IRGC Risk Governance framework

For this comparison the findings of the interviews with the producers[6] of the three cases are used. In **Appendix II** the comparison with the IRGC framework, for each case study, is described in detail. The identified strategies of the three cases showed in the comparison with the IRGC frame work per case a different picture, but also some similarities. In table 5 the percentages are presented for each case study where the principles of the IRGC framework are met per subject. In the pre-assessment and characterisation step, the identified strategies corresponded in all the three cases less than 50% with the principles of the IRGC framework. In the management step, two cases corresponded less than 50%. In the cross cutting aspect the best score was found in all the three cases.

Table 5. *Comparison with the IRGC Risk Governance framework (in %*).*

IRGC RG Framework subject:	Case study A	Case study B	Case study C
Pre-assessment (orientation) 6 items	**42%**	**25%**	**33%**
Risk Appraisal (taxation) 9 items	**55%**	**39%**	**55%**
Characterisation and evaluation (making choices) 6 items	**25%**	**8%**	**25%**
Management (control) 5 items	**30%**	**40%**	**60%**
Cross cutting aspects (stakeholder involvement) 5 items	**80%**	**80%**	**70%**

*Calculation %: meets item: score = 1, partially meet: score = 0.5, does not meet: score = 0. Add and divide score by total number of items * 100. **< 50%, 50- 75%, >75%.**

[6] Only the results from the interviews with the producers have been used because they apply most of the strategies in all three cases and can best be compared with each other as equal stakeholders.

The comparison shows that the following subjects, to varying degrees, were incompletely applied:

- Structural approach with responsible file holder.
- Risks inventory.
- Future analysis or horizontal scanning techniques for emerging risks.
- Use of multidisciplinary experts in risk identification / assessment.
- Prior consultation with all chain partners.
- Inventory of social, organizational and anthropological objections from stakeholders.
- Risk classification based on complexity, uncertainty and ambiguity.
- Weighting criteria for acceptance.
- Limits on the assessment and evaluation with regard to scope, scale and time horizon.

3.2 Motivations and barriers

It is striking that in all three cases almost the same motivations and barriers for applying strategies are mentioned. In summary, see also table 6, three primary motivations and several secondary motivations that support these primary motivations can be distinguished.

Table 6. *Identified primary and secondary motivations for applying risk strategies.*

Primary motivation	Secondary motivation
Secure properties of the end product	Selection at the gate (raw material)
	Closed chain of partners
	Prevent defective production
	Secure continuity and quality
	Secure image of the product
	Final checks, insure composition
Safety of the end product	Comply to legislation
	Selection at the gate (raw material)
	Closed chain of partners
	Preventing errors in production and use processes
	Final checks, insure safety
Profitable business model	Selection at the gate (raw material)
	Closed chain of partners
	Efficient processes
	Secure continuity and quality
	Secure image of the product
	Marketing, informing the consumer about the properties.

Seven overarching barriers can be distinguished from the information collected. These are listed in random order in table 7.

Table 7. *Overview of the main barriers for applying risk strategies.*

	Main barrier
1	Costs
2	Availability of raw materials and reliable suppliers
3	Labour intensive
4	Confidentiality, trade secret
5	The bureaucracy of research and acceptance
6	A lot of coordination due to "in house" or "closed chain" partners approach
7	Not profitable, increases the purchase price for the consumer

In table 8 an overview is given of the identified risks, the applied risk management strategies. Also the mentioned motivation(s) and barrier(s) per applied strategy are included in this table.

Table 8. *Overview of the identified risks, the risk management strategies and the mentioned motivations and barriers.*

Identified risk	Risk management strategy	Applied by (n)	Motivation	Barrier
Presence of hazardous substances in the end product.	All raw materials must be supplied with an analysis certificate and if applicable a DOC for use to come in contact with food.	Producer (2)	Selection at the gate. Delegating responsibility.	Availability of raw materials. It is difficult to find reliable suppliers who can deliver on time, with consistent quality and for a reasonable price.
	Selection and quality control of plant material on location during and after harvesting.	Producer (1)	Selection at the gate.	Arranging an independent physical check at various locations worldwide.
	Only use raw materials and additives that are on the positive list of the regulation (EC) 10/2011 and therefore are allowed to use for the production of plastic materials intended to come into contact with food.	Developer (3) Producer (3)	Comply with legislation. Accepted safety.	Inhibits innovation, acceptance process new substances / techniques takes too much time. The bureaucracy of research and acceptance.
	Database with information of all used raw materials and additives .	Producer (1)	Properties and the permitted application possibilities are known.	People and means to keep up.
	Calculation tool is used to be able to model the risks and properties of the final product.	Producer (1)	Chose the most efficient and safe recipe.	Database accuracy. Effect on the properties of the end product not predictable.
	Internal insurance process that all recipes are applied correctly.	Producer (1)	Precaution measure, prevent defective production.	None, standard procedure
	Composition analysis of end product.	Producer (3)	Final check. Want to know what's in it. Comply with legislation.	Confidentiality, trade secret. Costs for the laboratory testing and analyses. Detection limits. Extent of the investigation. Obligatory protocols.
Migration of hazardous substances to the food to be packaged.	Performing migration tests.	Producer (3)	Deliver a safe product. Comply with legislation.	Costs for the laboratory testing and analyses. Extent of the investigation. Obligatory protocols.
Change in the properties of the end product.	Internal insurance process that all recipes are applied correctly.	Producer (1)	Precaution measure, prevent defective production.	None, standard procedure
	Composition analysis end product.	Producer (3)	Final check. Want to know what's in it. Comply with legislation.	Confidentiality, trade secret. Costs for the laboratory testing and analyses. Detection limits. Extent of the investigation. Obligatory protocols.

Identified risk	Risk management strategy	Applied by (n)	Motivation	Barrier
Unsafe food due to inadequate packaging.	Shelf life tests.	Food packer (2)	Control of effective packaging.	Costs for the laboratory testing and analyses.
	Clear process instruction for the staff.	Food packer (1)	Preventing errors in the process.	Introduction of additional work instructions. Employability of staff.
	Final inspection per batch to control the risks.	Food packer (2)	Control of the sealing process and check on breakage.	Labour intensive. Extra critical points due to properties of the packaging material.
Continuity in production and quality.	Selection and quality control of plant material on location during and after harvesting.	Producer (1)	Every harvest can differ in quality. Determine yourself.	Reliable knowledge and expertise on location.
	The raw materials must come from producers with a GFSI recognized certificate.	Producer (2)	GFSI certification guarantees continuity and quality	Not feasible for all partners.
	"in house" approach, development and production in collaboration with regular partners.	Producer (3) Developer (3) Food packer(2)	Confidentiality, trade secret. Integral risk policy. Traceability. Closed chain.	A lot of coordination, head office policy is decisive. Often other partners are still needed.
	Use of material only under licence.	Producer (3)	Secure quality and safety. Secure image of the product (sustainability, bio-based and compostable). Closed chain.	Harder to find suitable partners. Set up and implement a control system to test partners for compliance with license agreements.
Disruption of waste flows.	Development of a special waste line.	Producer (1) Waste processor (1)	Products can be separated and processed for recycling or industrial composting.	Not profitable, supply and demand still too small.
	Separate waste stream.	Food packer (1)	Lower waste costs through separate collection. Act environmentally conscious.	No standard waste product, difficult to find processor.
	Campaigning towards the consumer.	Producer (2) Waste processor(1)	Informing the consumer about the properties and how it should be treated after use.	Too many similar products, too difficult for the consumer.
	Introduction of own recycling system, based on deposit on product.	Producer (1)	Act environmentally conscious. Product image.	Not profitable, hard to find partners, supply and demand still too small. Increases the purchase price for the consumer.
	Clearly recognizable logo.	Producer (3)	Recognisability. Marketing. Creating correct waste stream.	The use of official and unofficial logo's in the market. Logos are not sufficiently noticed. Logos are unknown to the public. No separate collection service available.

3.3 Indication of potential chemical risks

Eighteen randomly sampled bio-based plastic FCM have been analysed. In **Appendix III** the methods and the results are described in detail. The samples were subdivided in three groups, based on their main content. Group 1(n=10) consists mainly of (c)PLA, group 2 (n=5) consist mainly of cellulose fibre compound and group 3 (n=3) consists of combinations of PLA, cellulose fibre compound or others mixtures. In table 9 a short description and the group layout is given of the eighteen FCM samples. In all the three groups an indication of potential chemical hazards were found. Table 10 gives a general picture of the results of the analyses per group.

***Table 9**. Short description and group lay out of the 18 FCM samples.*

Sample description	Appearance	Main content
Group 1 (PLA)		
Bowl (tableware)	Transparent plastic	Polylactic acid
Spoon	White plastic	Polylactic acid
Cup (tableware)	Transparent plastic	Polylactic acid
Container for meat	Transparent plastic	Polylactic acid
Container for meat	Green plastic	Polylactic acid
Cold drinks cups	Transparent plastic	Polylactic acid
Coffee cup	White plastic	Polylactic acid
Packaging film	Printed plastic	Polylactic acid
Packaging film	Printed plastic	Polylactic acid
Cup (tableware)	Brown paper	Polylactic acid
Group 2 (Cellulose fibre compound)		
Snack tray	Brown cardboard	Cellulose fibre compound
Plate (tableware)	White cardboard	Cellulose fibre compound
Plate (tableware)	White cardboard	Cellulose fibre compound
Tray (tableware)	Beige cardboard	Cellulose fibre compound
Fork	Naturally woody	Cellulose fibre compound
Group 3 (Combinations)		
Bread bags	Brown paper with transparent plastic	Cellulose fibre compound and Polylactic acid.
Tray (tableware)	Inside white, outside brown cardboard	Cellulose fibre compound and Polylactic acid.
Tray (tableware)	Naturally woody	Inside cellulose fibre compound, outside Kantstik Q powder (lubricant)

***Table 10**. Overview samples (in %) per FCM group, in which substances/metals are found that stand out.*

Presence of	Group 1 (n=10)	Group 2 (n=5)	Group 3 (n=3)
Lactic acid. Mono-, di- and oligomers	60%	0%	0%
Substances that are not authorized	70%	100%	100%
More than 5 different metals	80%	100%	100%
More than 10 different metals	50%	60%	100%
Aluminium	100%	100%	100%
Aluminium > 1000mg/kg	40%	0%	33%
Mercury	60%	80%	100%
Cadmium	80%	80%	100%
Arsenic	10%	20%	0%
Lead	20%	40%	33%

The analysis consisted of a screening for the presence of NIAS and metals. Various unauthorized substances were found in more than 70% of the samples. Even substances that are classified according to their properties into a hazardous category were detected in some samples. For example the monomer octamethylcyclotetrasiloxane (CAS 556-67-2) was found in one of the samples. This substance is suspected as reproductive toxic. Also the potential carcinogenic substance 1-chlorododecane (CAS 112-52-7) was found in one sample. Other substances (not authorized) have been found that belong to the following notable chemical or application substance groups: Monomers, plasticizers, additives, fragrance and flavor substances, plant sterols, fatty acids and fatty acids amides.

The analysed FCM samples all contain various metals. In more than 50% of the samples more than ten different metals were found. In addition to aluminium, which was present in all samples, potentially toxic metals such as lead, arsenic, cadmium and mercury were found in several samples.

Despite the fact that the substances found have not been confirmed and the concentration of these substances has not been determined, it is clear that the findings indicate that there are potential indications for possible chemical risks in most of the analysed samples. In order to determine whether there is actually a risk, further research is needed with regard to the actual concentration and the migration properties of the indicated substance or metal.

3.4 Strengths and weaknesses

Based on the information gathered from the interviews held with the stakeholders of the three cases, the discussions with the experts and the outcome of the workshop, the strengths and weaknesses of the applied strategies were examined. The objective of this analysis is to assess the suitability of the identified strategies as elements of a best practice. Based on the assessment of the completeness, the effectiveness and the applicability of the 19 identified strategies a suitability score as a best practice is assigned to each strategy.

Despite the fact that the study showed that most strategies are only partially applied, seven strategies have been scored as very suitable as a best practice if they are applied correctly and fully. For these strategies it has been established that in general they can be applied relatively easily and contribute to a certain extent to the prevention of risks or to help manage identified risks. This score is awarded because: 1) the implementation is possible for all relevant stakeholders in the life cycle, also for small companies, 2) they provide a good coverage, within a specified group of risks, for the identification of possible risks that must be controlled and 3) they are effective, the risks are avoided or managed .

Also seven strategies have been scored as suitable. This score is mainly based on the fact that these strategies also contribute to a certain extent to the prevention of risks or to help manage identified risks but have dependencies that determine the effectiveness. Stakeholders cannot do this alone and the effectiveness is depending on actions and information from others.

Five strategies were scored as unsuitable or not suitable at all. It has been established that these strategies are not applicable for all stakeholders, they are relatively expensive, they have a large organizational burden and last but not least they do not adequately cover the risks. In table 11 an overview is given of the score, with a motivation, per identified strategy.

***Table 11**. Suitability score and motivation per identified strategy.*

	Identified risk management strategy	Score*	Motivation
1	All raw materials must be supplied with an analysis certificate and if applicable a DOC for use to come in contact with food.	++	Beware of the completeness of the certificate, the used methods and detection limits. Also secure that the certificate is reliable and representative for the supplied materials.
2	Selection and quality control, by own staff, of the plant material on location during and after harvesting.	--	Only applicable at locations known in advance. Physical checks at various locations worldwide are expensive and hard to arrange. Does not cover all possible risks.
3	Only use raw materials and additives that are on the positive list of the regulation (EC) 10/2011 and therefore allowed to use for the production of plastic materials intended to come into contact with food.	++	Save option, no acceptance process needed for new substances. In compliance with legislation. Form of accepted safety.
4	Database with information of all used raw materials and additives.	+	Availability, actuality and quality of the information in the database determine the reliability and completeness.
5	Calculation tool to model the risks and properties of the final product based on data input used raw materials.	+	Only applicable in combination with a database. Database accuracy and validation of the tool is essential. Effect on the properties of the end product is not only dependent on the used raw materials. Risks modelling is based on known risks. Not commercial available? Only " in house" version.
6	Internal insurance process that all recipes are applied correctly.	++	"four eyes" principle, reduces the change of mistakes, relative easy to implement. Increases the workload, but also makes staff more involved.
7	Composition analysis of end product.	++	Only if it concerns a complete analysis done with the appropriate methods. Also all substances found must be assessed for their possible risks.
8	Performing migration tests.	++	Only if it concerns a complete analysis done with the appropriate methods. In compliance with legislation. Form of accepted safety.
9	Shelf life tests.	-	Depending on the objective. It is usually about guaranteeing the microbiological safety of the product to be packaged. Other risks are not covered.
10	Clear process instruction for the staff.	++	Instructions only work if they are followed. Introduction programs, training and supervision must therefore be arranged.
11	Final physical inspection per batch to control the risks.	-	The objective of this strategy is usually about guaranteeing that the packaging is correct and that there are no visible defects. Other risks are not covered. Labour intensive.
12	The raw materials must come from producers with a GFSI recognized certificate.	--	GFSI certificate guarantees in general good manufacture practice and quality of the delivered products. GFSI certification is not of interest for many raw material suppliers outside the food chain. Despite GFSI certification you will still have to determine the risk of the raw materials yourself based on the composition.
13	"in house" approach, development and production in collaboration with regular partners.	+	This approach does ensure the corporate philosophy, "short lines" and clear decision-making in risk management. It will also contribute to the stability of the production process and promote stakeholders involvement. The disadvantage of this approach is that all activities are internally focused and that risks are usually kept within the organization.
14	Use of material only under licence.	-	This strategy ensures that you retain influence on the use of the product and can therefore control the risks of abuse. It can be used for risk management, but that is often not the primary goal. In addition, it is a legally and administratively heavy tool that will not be used by most companies.
15	Development of a special circular waste line.	+	This is an example of a control measure that should actually be taken collectively by the sector itself and is only applicable if the waste stream has sufficient volume. This strategy is not feasible for the average producer, only in collaboration with other stakeholders.

	Identified risk management strategy	Score*	Motivation
16	Separate waste stream for the bio-based materials.	+	By properly separating the waste streams, it becomes possible to properly organize reuse and recycling processes. There must, however, be an infrastructure to be able to process this waste stream.
17	Campaigning towards the consumer.	++	An essential part of good risk governance is informing the society and in particular the consumer about the advantages and disadvantages of the product. This allows society to determine for itself which risks are acceptable and how they should / would like to deal with them.
18	Introduction of own recycling system, based on deposit on product.	+	This is also an example of a control measure that should actually be taken collectively by the sector itself and is only applicable if the waste stream has sufficient volume. This strategy is not feasible for the average producer, only in collaboration with other stakeholders.
19	Clearly recognizable logo's on end product.	+	Logos are useful for quickly informing consumers about the characteristics and production methods of products. On the other hand, there are many logos that look alike and promise everything. The average consumer does not know the background of the many logos and the reliability of the logos is also often under discussion. Clear, globally applied logos that may only be used on the basis of an independent assessment can guarantee consumer confidence. Then they can also contribute to a responsible choice and conscious waste separation.

*: -- Not suitable at all, - not suitable, + suitable, ++ very suitable as best practice.

3.5 Roles and responsibilities

All stakeholders in the lifecycle of bio-based plastic FCM who have contributed to this research took into account possible health risks that their products or processes could cause. They fill in their responsibility by ensuring that laws and regulations are complied with. Usually the focus of their role and responsibility is only for their own part of the lifecycle, based on possible health risks known in their professional field. In doing so, they only take known risks within their own area of knowledge and their own circle of professional partners in account. No active research activities, from various angles and expertise, to identify potential new risks or identify possible factors that could create or influence risks were structurally done.

Based on the information gathered from the interviews held with the stakeholders of the 3 cases, the discussions with the experts and the findings of the workshop it was determined that the responsibilities in the lifecycle of bio-based plastic FCM is very fragmented. There is no stakeholder who has control and oversight over the complete lifecycle. Every stakeholder takes the responsibility for his or her part, while relying heavily on the responsibilities of others through demanding guarantees from the predecessor in the lifecycle and move within the assumed safety of the framework of legislation and regulations. The most frequently heard statement was: I make sure that I comply with the law and therefore my raw material/ additive/ process/ product/ application is safe!

The following aspects have been determined for each stakeholder, with regard to avoiding, reducing or constraining the known, but also the possible new and emerging, risks that can appear by introducing innovative new food contact material:

The suppliers of the raw materials; These stakeholders guarantees the quality of his product and indicates this through quality certification. Examples are guarantees about % bio-based and % (active) substance and sometimes a complete overview of the composition. Also if applicable, it is stated that it is suitable for use in the production of FCM. The supplier's responsibility ends when the raw material is delivered.

The suppliers of the additives; The same applies to these stakeholders as to the suppliers of the raw materials. The quality of the product is also guaranteed through quality certification. Guarantees about % bio-based and % (active) substance are also common here. In addition, it must be stated here that the additive is suitable for use in the production of FCM. The supplier's responsibility also ends after the product has been delivered.

The developers; The findings in this group are twofold. On the one hand, there are developers who do not want to be inhibited by legislation and regulations and pre-eminently risk-avoiding thinking. They claim that this inhibits innovation. They do take chemical, toxicological and technical risks into account, but the main focus is the development of bio-based and circular innovative materials and techniques. On the other hand, developers indicate that they only work with substances that may be used for the production of FCM. Substances or processes are excluded in advance because they do not comply with FCM legislation (not on the positive list). Regarding responsibility, advice and control measures are provided: what are the sensitivities and shortcomings. Often these are technological issues, which were recognized during the investigation as important to take into account. But with regard to the final product, it is up to the producer to create a technical file and to comply with the legislation.

The producers of the end materials; This group is aware of their legal duty to market safe products. They therefore demand guarantees from their suppliers, ensure good production practices and ensure that their end product complies with the laws and regulations. They take their responsibility by guaranteeing the quality and safety of their end product through certification and declarations that they meet the legal requirements. Clear instructions for use are also provided. Here too, responsibility often ends when the product leaves the factory. The producers are, however, proactively working to inform society about the advantages and disadvantages of their products. Information is provided through sector organizations.

The food packers; The packers guarantee that the food they pack is safe. In addition, the packaging must remain intact under normal conditions of use until the expiry date of the food to be packaged. They do this by requiring a statement from the supplier that the packaging material is suitable for packaging foodstuffs and by carrying out shelf life tests on the packaged foodstuffs. Their responsibility focuses primarily on the use of the appropriate packaging material and the microbiological safety of the packaged food.

The consumers; This group of stakeholders was not interviewed in this study. In general the responsibility of the consumer lies in making conscious choices that will influence the demand for bio-based FCM. Consumers also have a responsibility with regard to the correct use of the materials and to offer them to the waste processor in the correct manner.

The waste processors; In the life cycle of bio-based FCM, the waste processors are an essential factor when it comes to achieving the sustainability goals. They have a responsibility in contributing to achieve the recovery of raw materials, the recycling of the materials and, where applicable, in composting. They mainly look at the quality and composition of the waste streams offered. Based on this, they decide which processes can be applied. In practice it appears that, partly due to the small amount, most bio-based FCM are not processed separately. Where possible they go along with the existing waste processes or are incinerated as residual waste. They are bound by rules with regard to avoiding risks. There are strict requirements for the reuse of recycled materials for application as FCM and for compost

The government; Although the government is not directly an active player in the life cycle, it does play an important role. In addition to setting the legal requirements that must be met, the government is also responsible for supervision and can remove or ban products from the market. The government can also stimulate developments by introducing subsidies or other support measures. Thereby it can also set requirements for the actual sustainability profit and even impose the obligation to apply a form of risk governance to ensure that a sustainable and safe product is placed on the market as far as possible. The Dutch government cannot operate on its own. It will have to take into account European policy and guarantee an equal playing field. In addition, the government will also have to anticipate to these new developments and innovations. The legislation for the use and introduction of these innovations must be regulated relatively quickly and legislation that is outdated must be adapted to the new insights.

5. Conclusions, discussion and recommendations

5.1 Conclusions

The findings of this research show that the answer to the first part of the central research question "*Is the concept of risk governance implemented in the life cycle of new sustainable bio-based plastic food packaging materials?*" is no. The concept of risk governance is not really known by the interviewed representatives of the stakeholder groups. It is not implemented as a part of normal business operations for all interviewed developers and entrepreneurs in the life cycle of bio-based plastic food packaging materials.

A true risk inventory and identification strategy, one of the basic principles of risk governance, could not be identified in all three cases. Risk identification was done on the basis of generally known risks from the professional field. In doing so, they only take known risks within their own area of knowledge and their own circle of professional partners into account. No research activities were systematically performed, from various angles and expertise, to identify potential new risks or identify possible factors that could create or influence risks. In all three cases, no overview of the identified risks was available. The risks that were mentioned were very generally defined. Because risks were only mentioned in a general sense, the factors that determine the risks seem to be unknown.

The second part of the central research question "*are the strategies that are commonly applied in this life cycle, to control risk migration in relation to public health, sufficient?*" cannot be answered unambiguously, this requires more research. Strategies are applied and measures are being taken to prevent and control risks, but it has been established that they are incomplete in various areas, as will also appear from the conclusions below.

Despite the fact that no systematic form of risk governance was present in the three case studies, risk strategies are being applied, but these are usually not fully implemented. Choices are primarily determined by the information available and the financial resources. Nineteen different risk management strategies to avoid or control risks have been identified. These strategies are mainly applied to control the risks with regard to maintaining stability and continuity of product properties, to ensure a profitable business model and to be able to comply with legislation (the three main motivations). The findings show that the strategies to prevent or control public health risks are mainly applied to comply with legislation. Although experiences and literature have shown that compliance with laws and regulations is insufficient to prevent unforeseen risks, the stakeholders assumed that by complying with legislation the product is safe.

Insufficient sharing of information due to trade secrets, lack of financial resources and lack of sense of necessity, seem to be the main reason for the incomplete implementation of the strategies used.

In the comparison with the IRGC risk government frame work, the following subjects, to varying degrees, were incompletely applied:

- Structural approach with the designation of a responsible file holder.
- Risk inventory.
- Future analysis or horizontal scanning techniques for emerging risks.
- Use of multidisciplinary experts in risk identification / assessment.
- Prior consultation with all chain partners.
- Inventory of social, organizational and anthropological objections from stakeholders.
- Risk classification based on complexity, uncertainty and ambiguity.
- Weighting criteria for acceptance.
- Limits on the assessment and evaluation with regard to scope, scale and time horizon.

The barriers mentioned not to apply extensive risk governance, are summarized by the following statements: "it is too expensive", "it takes too much time", "it gives an administrative burden", "I do not want to share my professional secrecy" and "it is difficult to find reliable partners".

The findings of the chemical analysis indicate potential health hazards in most of the analysed samples. Various unauthorized substances were found in more than 70% of the samples. Even substances that are, according to their properties, classified into a hazardous category were detected in some samples. The analysed FCM samples all contain various metals. In more than 50% of the samples more than ten different metals were found. In addition to aluminium, which was present in all samples, potentially toxic metals such as lead, arsenic, cadmium and mercury were found in several samples. By confirming the presence of these substances and determining their concentration/migration, the risk should be characterised. With a properly functioning risk governance structure, it should be known that these substances are present in the end product, where they come from and that they represent an acceptable or no risk.

The number of potential chemical hazards appears to be slightly higher in the samples that consist mainly of cellulose fibre compound and in the samples that consist of combinations than in the samples that consist mainly of PLA.

The strength and weakness analysis of the 19 applied strategies showed that the following seven strategies, if fully implemented, are considered to be potentially very suitable as a best practice.

1. Supply all raw materials with an analysis certificate and if applicable a DOC for use to come in contact with food.
2. Only use raw materials and additives that are on the positive list of the regulation (EC) 10/2011.
3. Use an internal insurance process so that all recipes are applied correctly.
4. Perform composition analysis of end product.
5. Perform migration tests.
6. Clear process instruction for the staff. Arrange introduction programs, training and supervision.
7. Inform the society and in particular the consumer about the advantages and disadvantages of the product.

The responsibilities for the safety in the life cycle of bio-based plastic food packaging materials are very fragmented. None of the stakeholders has control and oversight over the complete lifecycle. Every stakeholder takes the responsibility for his or her part, while relying heavily on the responsibilities of others trough demanding guarantees from the predecessor in the life cycle. In addition, they generally assume that the framework of legislation and regulations leads to safety.

The lessons that can be learned from this study, to improve the risk governance in the life cycle of bio-based plastic food packaging materials are:

- Implement risk governance principles as a structural part of the business operations.
- Look beyond each own professional field. Implement active research activities, from various angles and expertise, to identify potential new risks or identify possible factors that could create or influence risks.
- Involve all chain partners in advance and discuss the feasibility of expected benefits of the product and the management of potential risks involved in the life cycle.
- Laws and regulations provide direction and help to avoid or control known risks, but it is unrealistic to expect that by complying with the legislation the product is safe. This is especially true for innovative products that are not yet aligned with legislation
- More transparency, complete openness and sharing honest information is essential to assess and manage risks.

5.2 Discussion

The results of this study are largely based on interviews with representatives of the different stakeholders groups of three study cases and experts reflections on the subject. The results should be treated with some care. The three study cases represent only a limited part of the available bio-based food packaging material on the Dutch market. Also the number of interviewed stakeholders and the number of consulted experts were limited. Therefore, the results are not necessarily representative. Nevertheless, it can be said that the results provide insight into the extent to which risk governance is applied in the life cycle being studied. Eight stakeholders and nine experts participated in the interviews. This is within the range that is usually aimed for in expert elicitations; 6-12 participants (Knol, Slottje, van der Sluijs, & Lebret, 2010).

To promote the validity and reliability of the interviews a standard framework was used. The same background information was sent to all interviewed persons in advance and the people were interviewed at their workplace. It was also indicated that the information will be processed anonymously and as confidential. Nevertheless, it cannot be excluded that the answers to the questions are coloured by personal views and circumstances. Perhaps socially or economically desirable answers have been given and not all information has been shared. Despite this possible information bias, it appeared that during the verification of the findings in the workshop with stakeholders and experts, the information was recognized and confirmed. The results of the interviews therefore seem representative for the life cycle being studied.

This study did not investigate the safety of bio-based food packaging materials. The focus of the research was on the applied risk governance strategies. The conclusion that the applied risk governance strategies are insufficient in the life cycle of bio-based food packaging materials does not mean that immediate action must be taken or that the materials investigated are unsafe. The consulted stakeholders are aware of their responsibilities and they are convinced that their products are safe. The mandatory migration tests also indicate that the materials, if used correctly, meet the safety requirements.

The state of affairs as found within the life cycle of bio-based FCM has not been compared with life cycles of other sustainable or traditional products. Therefore no statement can be made as to whether the situation is better or worse than with other life cycles.

The terms "hazard" and "risk" are often used interchangeably. However, in terms of risk assessment, these are two very distinct terms. The term risk is interpreted in various ways. The definition of the IRGC was taken as the starting point for this study. Another commonly used general definition of risk is well described in the Risk Assessment Manual of the Irish Health and Safety Authority (HSA, 2016), *" Risk is the chance that someone will be harmed by the hazard. It also takes account of how severe the harm or ill health could be and how many people could be affected*". Hazard is described in this manual as "*Anything with the potential to cause injury or ill health, for example chemical substances, dangerous moving machinery, or threats of violence from others*". Toxicologists use the following mathematical analogy to talk about risk: Risk = Hazard x Exposure (TEF, 2019). This formula must be taken into account when interpreting the results of the chemical analysis. In order to determine whether there actually is a risk, further research is needed with regard to the actual exposure to the potentially hazardous substances and metals that were found in the analysis.

Only a limited chemical analysis was performed. The objective was to see whether there was an indication of possible chemical hazards in the products examined by looking at the presence of unauthorized and/or potentially hazardous substances. A general screening was carried out, but no specific search for substance groups such as plant protection products, polycyclic aromatic hydrocarbons (PAHs), perfluoroalkylated substances (PFAS) and primary aromatic amines. The fact that these substances were not found does not mean that they were not present in the analysed samples.

Not sharing information is a major source of risk, but it is also understandable: sharing information takes effort and may conflict with competitiveness. For example: insight into all the substances present in raw materials, semi-finished products and end products, in all links in the chain, is essential to be able to make a proper assessment of the possible risks of the process and the materials now and in the future. If this is not known, a snowball effect can arise from an ever-increasing unknown amount of contaminants present. In addition, when finding unwanted substances in the end product, it will be a challenge to find their source, if it is not known what the complete composition of the raw materials or semi-finished products was.

The findings of this study show that apparently not much has changed since the study done by van der Sluis et al. (2013). Although only the life cycle of bio-based plastic food packaging materials has been investigated here, it seems that the same factors that van der Sluis et al. found still play a role in the introduction of new sustainable products and technologies in the transition to sustainability. Innovation is driven by competition between firms in a globalized economy and is aimed at achieving some sort of sustainability objective. Current innovation and production practices do not systematically account for potential unexpected risks. It is claimed by the producers, that it would harm the competitive position of the company unless all firms would have to go through such thorough explorative appraisal of new and emerging risks. All stakeholders in the life cycle aim to deal with clear and known types of risk and try to make sure that they comply with existing regulations. The identified barriers for applying extensive risk governance, such as; "too expensive" and "protection of the trade secrets" are in line with this economic claim. In addition to these economic factors, some other factors identified by van der Sluis et al., also play a role, as a result of which the application of risk governance is incompletely done. Personal and behavioural factors such as: 1) bias in appraisal of risks and benefits, 2) lack of sense of urgency, 3) limited expertise, 4) reluctance to act and 5) flaws in leadership are important barriers to implement full risk governance practices.

From a commercial point of view, it may not always be obvious but a joint approach within the chain could give many benefits. Sharing knowledge, coordinating research activities, building a product and risk strategy file together and working out a joint marketing plan prevent duplication of effort for each partner and can reduce the financial and administrative burden of applying good risk governance practices.

The IRGC framework for risk governance calls for a new thinking and conduct in governing risks. An inclusive approach to frame, assess, evaluate, manage and communicate important risk issues is essential. The fundamental idea of risk governance presupposes that the world is an assembly of physical, organic, social, and cognitive interactions and processes across various levels that are the sources and catalysts of generating, reflecting, and governing risks. It embraces the idea of interdisciplinarity as a means to integrate the physical as well as the social dimensions of risks, and enhances the notion of democratic decision making (Klinke & Renn, 2019). Interdisciplinarity, stakeholders (including government) involvement, transparency, societal experience and public wisdom are therefore necessary to include in the correct application of risk governance as intended.

It is an illusion to think that with the right risk governance, all risks can be prevented now and in the future. Unforeseen incidents will certainly occur. By applying good and complete risk governance strategies, companies take their responsibility and undertake structural and continuous actions as far as possible to avoid and control risks. Also, an accepted scientific and social balance can be established between the benefits and risks of the new process or materials before they are introduced .

5.3. Recommendations

It is recommended to conduct more research into the exact composition of the bio-based FCM and the possible exposures to the substances present. The results of the limited chemical research in this study give sufficient reason for the control authorities, to conduct more inspections combined with chemical analysis and migration tests, whereby it must be tested whether the declaration of compliance is complete and sufficiently substantiated.

In addition to the legal obligation to declare compliance with Regulation (EC) 1935/2004 and Regulation (EC) 10/2011, it is recommended to make it mandatory to specify the composition of raw materials, semi-finished products and end products on the DOCs. By making this mandatory you guarantee a level playing field, whereby it is natural to share the composition with each other. The alternative is that producers and buyers themselves have to ask for the complete composition. This can then be done in a kind of confidentiality. For this alternative, there will be more support because of the protection of trade secrets. The disadvantage of this method is that not all links in the life cycle, for example the waste processors, are well-informed and that it is likely that it will be difficult for smaller and/or less financially decisive players because additional costs will probably be charged by suppliers.

For the sector it is therefore recommended to seek cooperation, take control and take responsibility for the implementation of good risk governance with a chain director who ensures that good and complete risk governance is carried out, has an overview and ensures that the financial and administrative burdens are manageable for all partners. The trade association could support this and perhaps prepare guidelines and promote good practices.

Most authorities encourage initiatives to achieve a more sustainable society. When granting subsidies, it is recommended to include the condition that companies must demonstrate they implement risk governance practices in a structural manner and that a public file is available.

The development and introduction of bio-based food packaging materials is one of many initiatives in the transition to a sustainable society. In general, there seems to be little attention for possible risk migration during this transition. The sustainability goals are paramount. It is therefore recommended that also other initiatives during this transition be assessed for possible risks to public health and investigated for applied risk governance practices. Especially in the case of developments where new processes or materials are introduced, more attention to risk governance is desirable in order to find a good balance between the benefits and potential risks.

The IRGC framework for risk governance is very extensive and does not seem well suited for use by small and medium-sized businesses. Nevertheless in developing a more practical risk governance strategy it is recommended to use the principle of the Plan-Do-Check-Act management method (Maruta, 2012; Moen & Norman, 2010) and implement the 4 steps and the 3 cross cutting aspects from the IRGC framework in a continuous cycle. Businesses can adjust the implementation depending on their possibilities and the complexity of the subject. An example of such a relatively simple framework supplemented with some best practice strategies that can serve as a practical guide is presented in Annex IV. Figure 8 shows the proposed cycle in this framework schematically.

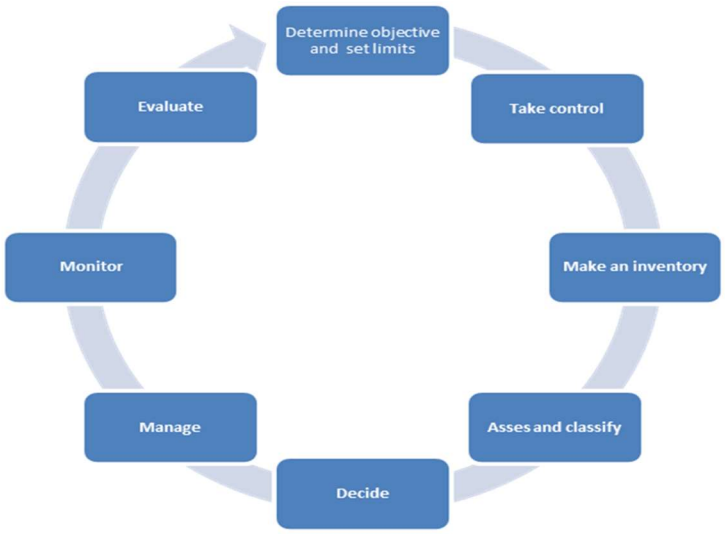

***Figure 8**: Schematical presentation of the proposed, more practical risk governance framework.*

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Appendix I

Interview framework

All information will be treated confidentially. In my research report the information will not be traceable to your company or product.

1. General questions

1 Does your company develop, produce or supply bioplastic packaging materials for foodstuffs?

2 Can you tell me more about your company? Is it a multinational, own production facility, own laboratory, patented material?

3 What is your function and role ?

2. Risk Assessment

4 Can you tell me how your organization deals with the risk assessment in the development, production or introduction of new FCM's?

5 Do you use an standard framework or procedure? Is this available?

6 What problems do you encounter when performing a risk assessment?

7 Do you know the Risk Governance framework of the International Risk Governance Council (IRGC)?

3. Material and product information

8 What was the last bio-based FCM your company was involved in or put on the market?

9 Is there a technical dossier available containing the information specified in the EFSA guidelines for the safety assessment of this substance or material?

10 Are supporting documentation, like the declaration of compliance and results of the migration testing available?

11 Is there an EFSA or other assessment/opinion available for this material?

12 Are there any restrictions in the use of the product?

13 Is the product certified? Is an certification report available?

4. Questions about the usefulness and necessity of the steps from the IRGC framework *(if appropriate, I will ask which questions have not been addressed and which ones are perceived meaningful)*

Step 1: Pre-assessment *(orientation)*

14 Do you think you know the risks as well as the opportunities that you are addressing with the introduction of this new FCM?

15 Who are the stakeholders? Do you use their views and their affection (emotion) to the definition and framing of the risks and opportunities?

16 Does your organisation use foresight or horizon scanning techniques for the identification of emerging risks?

17 Does your organisation involve multidisciplinary experts in the risk identification?

18 Does your organisation use the granting of various dimensions to the identified risks?

19 How does your company set the boundaries of the assessment and evaluation, in terms of scope, scale or time horizon?

Step 2: Risk Appraisal *(taxation)*

Scientific assessment

20 Have you made an estimate of the possible consequences of the identified risks? *What are the potential damages or adverse effects associated with the risk? How ubiquitous could the damage be? How persistent? Can it be reversed?*

21 Do you know which processes create and control the risks?

22 Do you quantify the identified risks? (e.g. as a function of probability and severity)?

23 Do you consider (worse case) scenarios in your risk appraisal? *Do risk assessors use scenario development for prospective assessment of the risk? What accident scenarios can occur? What about their severity, kinetics, probability of occurrence, etc.?*

24 How do you deal with uncertainties in the assessment? *Do you determine the degree of confidence in the risk assessment, including its comprehensiveness (inclusion of all relevant factors) and accuracy? What is the level of robustness and validity of data and knowledge? How reliable are the probability estimates and how much uncertainty prevails?*

Concern assessment

25 Do you know and use the different stakeholders' opinions, values and concerns about the risk? *What is their level of involvement, accountability or responsibility?*

26 Did you investigate if there are cognitive or heuristic biases that affect the risk perception or concern? *(Availability, status quo or choice avoidance, anchoring effect, personal experience and avoidance of cognitive dissonance)*

27 Did you identify sociological, organisational and anthropological constraints on actors and stakeholders? *What is the social response to the risk? How do people react? Is there the possibility of political or social mobilisation? What role do existing institutions, governance structures and the media play in defining and addressing public concerns?*

28 Is your organisation and are your risk managers prepared to face controversies and conflicts due to differences in risk perception, in stakeholder objectives and values, or from inequities in the distribution of benefits and risks?

Step 3: Characterisation and evaluation *(making choices)*

29 How do you make choices about the identified risks? *Do you characterise the identified risks in terms of complexity, uncertainty and ambiguity? Do you have criteria for 1)* ***Acceptability,*** *if risk reduction is considered unnecessary, 2)* ***Tolerability****, if the risk can be pursued because of its associated benefits, but subject to appropriate risk reduction measures or 3)* ***Intolerability****, if it must be simply avoided, i.e., no risk reduction measures can make it tolerable?*

30 Does your company consider ethical issues, beyond those taken into consideration in the concern assessment?

31 What are the societal values and norms for making judgments about tolerability and acceptability? Are these values and norms changing?

32 Are there constraints involved in the judgement (e.g. time, budget, context, etc.)?

33 How does decision-making come about? Who's in the lead? *Do any stakeholders – shareholders, (local)government, business or other – have commitments or other reasons for wanting a particular outcome of the risk governance process? Is account taken of the political or strategic appreciation of the societal, economic and environmental benefits and risks?*

34 If there is a possibility of substitution? How do you compare the risks? With aspects weight heavier?

Step 4: Management *(control)*

35 How does your company deal with organizing the management of the identified risks? *Do you select actors and stakeholders that should be involved in de risk management process? Do you make them responsible to a certain level? Do they accept this responsibility?*

36 How does your company choose between de various management options (e.g. technological, regulatory, institutional, educational, transfer, compensation, etc.)? *Do you use criteria for the possible options in the balance between impact on risk reduction and their costs and benefits?*

37 Do you take international cooperation and harmonisation for global, trans-boundary or systemic risks in to account in your decision process?

38 How are the options evaluated and prioritised? *What are the evaluation criteria? Do you consider potential trade-offs between risks, benefits and risk-reduction measures that may arise?*

39 How do you ensure that the management decision and actions are effective in the long term? *Do you use monitoring and/or enforcement tools? Does the risk management decision account for uncertainty and ambiguity, and does it enable some flexibility and adaptation if and when new knowledge is available?*

Step 5 : Cross cutting aspects *(stakeholder involvement)*

Communication process

40 Is there a facilitator in charge of the risk communication processes?

41 Is the internal communication process (in-house experts) organized and facilitated?

42 Is the external communication process (with and between risk takers, risk affected parties, regulators, the public, the media and other stakeholders) organized and facilitated?

43 How do you ensure that the communication process is organized in a way that two-way information is effective, enlightening and timely?

Communication content

44 How do you ensure that the information that you share is accurate? *What is known about the risk and the hazard, by whom, and how can it be conveyed to the interested stakeholders and the public?*

45 How do you deal with ambiguities and controversies about the risk within the public sphere? *Does the communication take into account how the risk is perceived by the stakeholders? What is the degree of confidence in the risk managers responsible for generating or disseminating information, and for organizing a dialogue?*

46 How do you to deal with confidential and sensitive information?

47 Do you know the demands, needs and purposes for information and communication among the different stakeholder groups, including members of the general public? *Are the concerns of stakeholders and the public being clearly articulated and are decision-makers listening (two way communication)?*

48 Do you verify how the information is interpreted by those who receive it?

49 Do you use the media for risk communication and increasing the stakeholders involvement, both traditional and social?

5. Completion of the interview

50 Did you recognise the 5 steps from the IRGC framework in your own procedures?

51 Do you look differently now at your risk governance processes after this interview?

52 Do you consider to implement the IRGC frame work? if not, could you tell me why?

53 Do you have any questions, comments or suggestions that I should include in my research?

Appendix II
Elaboration of the case studies

Based on the information obtained from the interviews and the received documents, for each case study the following items are addressed:

- Material description
- Description of the applied risk strategies
- Description of the experienced motivations and barriers in the applied strategies
- Description of the experienced and taken responsibilities
- Comparison with the IRGC Risk Governance framework

Only de findings of the interviews with the producers are used for this comparison, because these were most relevant in regards to bringing a safe product into the market by applying Risk Governance practices.

Explanation of the colours used in the comparison

	Meets basic principles
	Meets partially
	Does not meet basic principles

Case study A

Material description

The end product is used as a foil for packaging of frozen vegetables. The material is a polyolefin film mainly consisting of the basic polymers PE and PP. The end product is OK Bio-based certified (4 stars => 80%) by TUV Austria based on ingredient declaration. This is checked annually.

According to the Declaration of Compliance (DOC) for the article group[7]: polyolefin film coloured, the following monomers are used in the formulation:

FCM[8] nr. 231: Acetic acid, vinyl ester	**FCM nr. 264:** 1-octene	**FCM nr. 356:** 1-hexene

The following additives are used in the formulation

FCM nr. 19: N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	**FCM nr. 20:** N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides	**FCM nr. 53:** glycerol, esters with stearic acid
FCM nr. 69: phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	**FCM nr. 129:** ethylene oxide	**FCM nr. 132:** vinylidene fluoride
FCM nr. 176: acrylic acid, methyl ester	**FCM nr. 227:** ethyleneglycol	**FCM nr. 263:** diethyleneglycol
FCM nr. 282: hexafluoropropylene	**FCM nr. 411:** carbon black	**FCM nr. 433:** octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
FCM nr. 500: 2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	**FCM nr. 689:** 1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	**FCM nr. 715:** 3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt

[7] The producer uses one DOC for the whole group of polyolefin films produced. Not all mentioned substances are really used in specific cases. It is an overview of all possible used substances within this article group.
[8] FCM nr. = Food Contact Material Number listed in EU regulation 10/2011

FCM nr. 716: 1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	**FCM nr. 771:** aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phosphate]	**FCM nr. 779:** 9,9-bis(methoxymethyl)fluorene
FCM nr. 783: glycerides, castor-oil mono-, hydrogenated, acetates	**FCM nr. 793:** triethanolamine	**FCM nr. 923:** N,N-bis(2-hydroxyethyl)dodecanamide

The following metals are listed as present in the material:

Barium
Copper
Iron
Zinc

Which risk strategies are applied?

It is not a new product! The end product has been on the market for years, the only difference is the use of bio-based version of the monomers. So risk management is mainly focussed on the quality of the raw materials and the production process.
The producer only uses raw materials and additives that are on the positive list of the regulation (EC) 10/2011 and therefore are allowed to use for the production of plastic materials intended to come into contact with food. The producer requires all raw materials to be supplied with an analysis certificate and if applicable a DOC. Also the raw materials must come from GFSI certified producers. So the properties and the permitted application possibilities are assumed to be known.

The producer collects all this information in a database per raw material. Based on this data and the recipe he intends to use, a calculation tool is used to be able to model the risks and properties of the final product. If this modelling shows that, for example, the migration requirements are being exceeded, the recipe will have to be adjusted. The calculation tool is based on the SML and QM (SML = specific migration limit, QM = maximum amount in the material) for the raw materials. This calculation tool is validated by having end products examined for the overall migration and by mechanical tests such as tensile tests.

In addition, the producer has an internally auditing process that all recipes are applied correctly. This is guaranteed by a check by a second operator for the correct raw materials and settings for start-up. Also the first products are not used when starting up and changing the production line, because they may contain residues from the previous batch or start-up contaminants from the machines.

For the food packer, risk management involves ensuring of the appropriate packaging of the foodstuffs and the requirement be able to submit the correct documentation of compliance to regulations and information about allergens. In fact, practical and legal guaranties for the suitability of the material for packaging food (frozen vegetables). Requirement of guaranties from the supplier, shelf life tests and physical inspections of the packed foods are the applied strategies to avoid the mentioned risks

The IRGC framework is unknown, none of the people interviewed in the life cycle of this product knew the institution or model.

Which motivations and barriers in the applied risk strategy are experienced?

The main motivation for the producer is the market demand. No real barriers are experienced because the product is chemically not different from the fossil variant and the production process is also the same. The only barrier that was mentioned was the fact that the bio-based monomers and additives are offered by only a few suppliers and they are relatively expensive. It is difficult to find reliable suppliers who can deliver on time, with consistent quality and for a reasonable price.

Another barrier, which also applied for other end products, are the costs for the laboratory testing and analyses. That is why the producer groups the end products that consist of similar materials, only a few end products from this group are analysed. The results of this study then apply to the entire group, so not every product from every batch is tested.

The food packer mentioned the possible influence on the Overall Equipment Effectiveness (OEE) of the packaging machines and of course costs as a barrier.

Where is the responsibility placed?

In general, the purpose of the applied strategies is to ensure compliance to legislation. It is assumed that the product is then safe and that there are no risks to public health and the environment. The producer places the responsibility entirely with the body that draws up the regulations and the positive list.

The producer places the responsibility for the safety of the raw materials at the supplier. The producer takes the responsibility for the safety of the end product if it is used properly. Therefore the producer also makes agreements with the foodpacker about the correct use.

The food packer places the responsibility for the safety of the packaging material at the producer. The packer is responsible for the correct application and the correct combination of the food and the packaging. He is also responsible for the appropriate labelling and safe print techniques.

It is then up to the consumer to use the packaged food in accordance with the instructions and to dispose of the packaging material in the correct manner.

Comparison with the IRGC Risk Governance framework

The comparison results are shown in the table below.

IRGC RG framework subject	**Producer's statements**	**Comparative judgement**
Pre-assessment (orientation)		
Are the risks as well as the opportunities that are addressed with the introduction of this new FCM known?	Yes, the new product is chemically not different from the fossil variant.	Meets basic principles
Are stakeholders views and their affection (emotion) to the definition and framing of the risks and opportunities used?	Our stakeholders are our customers and raw material suppliers. We certainly take their ideas and opinions into account. The customer requirements are taken as a starting point and then we look with the customer and raw material suppliers on how we can best achieve this.	Meets partially: not all stakeholders in the life cycle are involved.
Are foresight or horizon scanning techniques for the identification of emerging risks used?	No.	Does not meet
Are multidisciplinary experts involved in the risk identification?	No.	Does not meet
Have different dimensions been assigned to the identified risks?	Yes, we have identified and weighed the risks.	Meets basic principles
Were there boundaries set in the assessment and evaluation, in terms of scope, scale or time horizon?	No.	Does not meet
Risk appraisal (taxation)		
Are the possible consequences of the identified risks estimated?	Yes, we have made an inventory of the risks in accordance with the BRC[9] requirement and have introduced control measures. Where the risks were not manageable, we looked for alternatives or decided not to include the product or production process in our range.	Meets basic principles
Is it known which processes create and control the risks?	Yes, based on our inventory	Meets basic principles

[9] BRCGS= British Retail Consortium Global Standards. This is a private certification scheme.

Are the identified risks quantified?	Yes, in accordance with the BRC requirement.	Meets basic principles
Are (worse case) scenarios considered in the risk appraisal?	Yes, when assessing the properties of the raw materials in our database, we assume the worst case conditions.	Meets partially: limited, misuse and end of life scenarios are not considered
How are uncertainties dealt with during the assessment?	We validate our theoretical modelling by regularly performing overall migration tests on a few products from the established similar group of products.	Meets basic principles
Are the different stakeholders' opinions, values and concerns about the risk known and used? What is their level of involvement, accountability or responsibility?	Yes, the responsibility for the safety of the raw materials is placed with the supplier, and agreements are also made with the buyer of the products about their use. The producer himself takes responsibility for the safety of the end products. Should something go wrong with the products, it can be investigated in the chain where things went wrong and that link in the chain is then reminded of his / her responsibility and addressed	Meets partially: not all stakeholders in the life circle are involved.
Are cognitive or heuristic biases that affect the risk perception or concern investigated?	No, not consciously. We do listen to our staff and provide clear instructions and background information to ensure that the production process runs as safely as possible.	Does not meet
Are sociological, organisational and anthropological constraints identified on actors and stakeholders?	No, it is a very general and widely accepted product that we make. Of course there are concerns about sustainability. That is why we ourselves also actively contribute to the discussion and policy making on sustainability and the recycling possibilities. For example, the possibilities of chemical recycling instead of or in combination with mechanical techniques.	Does not meet
Is the producer prepared to face controversies and conflicts due to differences in risk perception, in stakeholder objectives and values, or from inequities in the distribution of benefits and risks?	No not consciously, we do keep a close eye on the social debate about the use of plastic.	Does not meet
Characterisation and evaluation (making choices)		
Are the identified risks characterised in terms of complexity, uncertainty and ambiguity?	Not really, we set requirements for the raw materials and identify our production risks.	Meets partially: Limited scope
Are there criteria for acceptability, tolerability or intolerability?	Yes, It must meet the legal requirements and the raw materials must be of sufficient quality	Meets partially: Limited scope
What are the societal values and norms for making judgments about tolerability and acceptability? Are these values and norms changing?	We apply the principle of corporate social responsibility. We have a CSR certificate, but we do not really use this in the risk assessment.	Does not meet
Are there constraints involved in the judgement (e.g. time, budget, context, etc.)?	Yes, money and time are important. It must fit in with the business plan.	No Judgement, informative
How does decision-making come about? Who's in the lead?	Team R&D gives advice to the management. The management then decides whether or not to take it into production.	No Judgement, informative. Remark: Stakeholders have no vote.
If there is a possibility of substitution? How are risks compared ? With aspects weight heavier?	Team R&D seeks the most efficient recipe and production method based on customer requirements. The risks are also included in this search. Complying with legislation is the most important, then of course the costs and availability of the raw materials and production lines.	Meets partially: Limited scope, food safety and environmental burden is not mentioned

Management (control)		
How is the management organized of the identified risks?	See the previous answers for this. Suppliers and buyers have a responsibility.	Meets partially: Limited scope
How to choose between the various management options (e.g. technological, regulatory, institutional, educational, transfer, compensation, etc.)?	We clearly opt for risk management in advance. By selecting our raw materials at the gateway and good quality control in production, we think we can limit the risks to a minimum	Meets partially: Limited scope
Are international cooperation and harmonisation for global, trans-boundary or systemic risks taken in to account in the decision process?	No.	Does not meet
Are all options evaluated and prioritised? Are potential trade-offs between risks, benefits and risk-reduction measures that may arise, considered?	No, only in the R&D process for efficient production.	Does not meet
How are the management decision and actions effectivity in the long term assured?	We regularly examine our end products for composition. In addition, we keep our database of raw material properties up to date and we incorporate all new knowledge and insights into it.	Meets partially: Limited scope
Cross cutting aspects (stakeholder involvement)		
How is ensured that the communication process is organized in a way that two-way information is effective, enlightening and timely?	The R&D team is well trained and reliable. The information is properly investigated and verified before it goes out. Of course, stakeholders and the public are taken into account here, but we tell the true story, we have nothing to hide.	Meets basic principles
Are the demands, needs and purposes for information and communication among the different stakeholder groups, including members of the general public known?	Think so, as we have already indicated, we are open to this. We deliver a DOC with every product and if there are any questions about our products we try to answer them as well as possible.	Meets basic principles
Is there a protocol: How to deal with ambiguities and controversies about the risk within the public sphere?	No	Does not meet
How is confidential and sensitive information dealt with?	This does not play a role in risk communication, of course we respect the person and / or company confidentiality and sensitivities. We will also respect the privacy legislation, but we will be open about the possible risks if this were to happen with our products. This is also a BRC requirement, for example in the case of a recall.	Meets basic principles
Are the media used for risk communication and increasing the stakeholders involvement, both traditional and social?	Yes, we choose the most effective way.	Meets basic principles

Case study B

Material description

This product is used as a tray for fresh meat. The tray is made of PLA. The product is certified as bio-based (ASTM D 6866 > 85%) and as industrial compostable (DIN EN 13432) by DIN CERTCO.

According to the Declaration of Compliance for the article: PLA natur und Grün eingefarbt, the following monomers are used in the formulation:

FCM nr. 99: lactic acid

The following additives are used in the formulation

FCM nr. 175: methacrylic acid, allyl ester	**FCM nr. 156:** methacrylic acid, methyl ester	**FCM nr. 325:** acrylic acid, n-butyl ester
FCM nr. 411: carbon black	**FCM nr. 141:** 1,1,1-trimethylolpropane	**CAS nr. 0001328-53-6** polychloro copper phtalocyanine (pigment green 7)

The following metals are listed as present in the material:

Aluminium
Copper

Which risk strategies are applied?

The end product has been developed and is produced in collaboration with regular partners. These partners are almost all part of one holding company. This "in-house" approach makes it possible to implement an integral risk policy and to guarantee quality and continuity. Traceability is also guaranteed in the production stage.

This product consists of raw materials that are all on the positive list of the EU legislation. Therefore no EFSA permission is needed to market this product. The raw material supplier must provide the raw materials with a certificate proving that they are safe and may be used for applications in food packaging. Also GMP certificates are required from the processing links (printers and producers) and, where necessary, compliance statements with regard to EU legislation for plastic packaging for foodstuffs. The legally required migration tests are done and then it is assumed that the end product is safe and does not entail any risks.

The supplier is aware of the risks in the waste phase of this product that arise due to the unfamiliarity of the properties of this material. Therefore, he actively contributes by campaigning towards the consumer and by developing a waste line together with a waste processor in which PLA products can be separated and processed for recycling or industrial composting.

The packer mainly looks at the risks in the packaging process. He wants to be sure that gas packaging and sealing are going well. He also wants the packaging lines to be used without modification. In addition, the results of the shelf life tests are compared with those of the standard (conventional) packaging. Robustness tests are also carried out, the packaging must be able to withstand rough handling. In daily practice, clear process instructions for the staff and final inspection are arranged per batch to control the risks

The IRGC framework is unknown, none of the people interviewed in the life cycle of this product knew the institution or model

Which motivations and barriers in the applied risk strategy are experienced?

The ambition of the company is to bring sustainable packaging to the market. Together with the chain partners, products are developed and it is examined whether there is a market for it. Food packaging must by safe, the challenge was to develop suitable sustainable packaging for fresh meat products. The applied risk strategy aims to ensure that the end product complies with EU regulations and that quality is guaranteed.

The development of this product went through several intermediate products that always need to be adjusted slightly in order to ultimately have the right properties. The motivation and focus of these adjustments was on meeting end user requirements. The basic conditions to these adjustments were that the end product should be as bio-based as possible, only ingredients that are listed on the positive list of the EU regulation may be used and that the production costs kept manageable. The condition to reduce or prevent risks was secondary and only targeted on the fact that the end product complies with regulation.

The confidentiality of the product data was mentioned as a barrier. Agreements had to be made with all involved parties. Because of this the applied risk strategy was very internally controlled and not transparent.

The packer's motivation lies in the fact that he wants sell a safe product with a sustainable label. The packer experienced barriers due to the properties of the packaging material. In his food safety control plan he had to implement extra critical control points. The sealing process is insufficient in a fatty environment and due to the brittleness of the material there is a higher chance of breakages. Using this product also creates a new waste problem, a separate waste stream has to be implemented.

Where is the responsibility placed?

The producer places the responsibility for the safety of the raw materials by the supplier and ensures the safety of the end product by complying to EU legislation.
The food packer places the responsibility by the supplier of the end product. The packer himself takes responsibility for the proper packaging of the food that he puts on the market.

The responsibility for the waste phase is laid down by the consumer and the waste processor.

Comparison with the IRGC Risk Governance framework

The comparison results are shown in the table below.

IRGC RG framework subject	Producer's statements	Comparative judgement
Pre-assessment (orientation)		
Are the risks as well as the opportunities that are addressed with the introduction of this new FCM known?	We think we know the risks of this product. For example the use of plant protection products in the raw materials and the possible migration of (potentially dangerous) substances to food. We also see the risks at the end of life phase.	Meets basic principles
Are stakeholders views and their affection (emotion) to the definition and framing of the risks and opportunities used?	Our stakeholders are our customers and raw material suppliers. We certainly take their ideas and opinions into account. The customer requirements are taken as a starting point and then we look with the customer and raw material suppliers on how we can best achieve this.	Meets partially: not all stakeholders in the life circle are involved.
Are foresight or horizon scanning techniques for the identification of emerging risks used?	No.	Does not meet
Are multidisciplinary experts involved in the risk identification?	No.	Does not meet
Have different dimensions been assigned to the identified risks?	We do not deal structurally with risks, no identification, classification and evaluation	Does not meet
Were there boundaries set in the assessment and evaluation, in terms of scope, scale or time horizon?	No.	Does not meet
Risk appraisal (taxation)		
Are the possible consequences of the identified risks estimated?	No	Does not meet
Is it known which processes create and control the risks?	Three risks are clear to us and we know the cause. We therefore take precautions for this. Residues of plant protection products in our end product, only raw materials that are on the positive list of the EU and land use for the basic vegetable material.	Meets basic principles
Are the identified risks quantified?	No	Does not meet
Are (worse case) scenarios considered in the risk appraisal?	No	Does not meet
How are uncertainties dealt with during the assessment?	Not done.	Does not meet
Are the different stakeholders' opinions, values and concerns about the risk known and used? What is their level of involvement, accountability or responsibility?	Yes, the responsibility for the safety of the raw materials is placed with the supplier, and agreements are also made with the buyer of the products about their use. The producer	Meets partially: not all stakeholders in

	himself takes responsibility for the safety of the end products. Should something go wrong with the products, it can be investigated in the chain where things went wrong and that link in the chain is then reminded of his / her responsibility and addressed	the life circle are involved.
Are cognitive or heuristic biases that affect the risk perception or concern investigated?	No	Does not meet
Are sociological, organisational and anthropological constraints identified on actors and stakeholders?	We are aware of the societal discussions and therefore actively contribute to this discussion through my role in the trade association in which we bring the facts and fables surrounding bio-plastics to the attention of consumers and politicians.	Meets basic principles
Is the producer prepared to face controversies and conflicts due to differences in risk perception, in stakeholder objectives and values, or from inequities in the distribution of benefits and risks?	Yes, we do keep a close eye on the social debate about the use of plastic.	Meets basic principles
Characterisation and evaluation (making choices)		
Are the identified risks characterised in terms of complexity, uncertainty and ambiguity?	No	Does not meet
Are there criteria for acceptability, tolerability or intolerability?	No	Does not meet
What are the societal values and norms for making judgments about tolerability and acceptability? Are these values and norms changing?	We do not really apply social values and norms. We have our company policy to deliver safe and sustainable products.	Does not meet
Are there constraints involved in the judgement (e.g. time, budget, context, etc.)?	Yes, money and time are important. It must fit in with the business plan.	No Judgement, informative
How does decision-making come about? Who's in the lead?	Decisions are made by the management. Together with the chain partners, products are developed and it is examined whether there is a market for it.	No Judgement, informative. Remark: Stakeholders have no vote.
If there is a possibility of substitution? How are risks compared? With aspects weight heavier?	When developing products, we naturally look at various options for composition and method of production, comparing properties, costs and potential risks. Costumer requirements and complying with legislation are the most important, then of course the costs and availability of the raw materials and production lines.	Meets partially: Limited scope, food safety and environmental burden is not mentioned
Management (control)		
How is the management organized of the identified risks?	See the previous answers for this. Suppliers , producers and users have a responsibility.	Meets partially: Limited scope
How to choose between the various management options (e.g. technological, regulatory, institutional, educational, transfer, compensation, etc.)?	We clearly opt for risk management in advance and in providing correct information to society.	Meets partially: Limited scope
Are international cooperation and harmonisation for global, trans-boundary or systemic risks taken in to account in the decision process?	Not structural, but we operate internationally and of course we use the information and respect the interests of our international partners	Meets partially: Limited scope
Are all options evaluated and prioritised? Are potential trade-offs between risks, benefits and risk-reduction measures that may arise, considered?	No, not structural. In development, this will certainly be applied, but not to a predefined method.	Meets partially: Not structural
How are the management decision and actions effectivity in the long term assured?	No procedure.	Does not meet

Cross cutting aspects (stakeholder involvement)		
How is ensured that the communication process is organized in a way that two-way information is effective, enlightening and timely?	We actively promote our products, telling the honest story. We like to enter into a discussion and want to contribute with our product to a sustainable solution for packaging foodstuffs. We do this by being an active member of the branch association and where possible participating in the public and scientific debate.	Meets basic principles
Are the demands, needs and purposes for information and communication among the different stakeholder groups, including members of the general public known?	Think so, as we have already indicated, we are open to this. We deliver a DOC with every product and if there are any questions about our products we try to answer them as well as possible.	Meets basic principles
Is there a protocol: How to deal with ambiguities and controversies about the risk within the public sphere?	No	Does not meet
How is confidential and sensitive information dealt with?	This does not play a role in risk communication, of course we respect the person and / or company confidentiality and sensitivities. We will also respect the privacy legislation, but we will be open about the possible risks if this were to happen with our products.	Meets basic principles
Are the media used for risk communication and increasing the stakeholders involvement, both traditional and social?	Yes, we use all kind of media.	Meets basic principles

Case study C

Material description

This product is used as capsule for coffee that must be used in coffee making machines. The capsule is made of a patented bio-polymer matrix. The basic material of this product is declared as 100% bio-based and fully home compostable stated by a scientific report published in April 2019.

According to the Declaration of Compliance for the article: Biopolymer (BP), the following monomers and polymers are used in the formulation of the patented bio-polymer:

FCM nr. 99: lactic acid	**FCM nr. 553:** Cellulose	**CAS nr. 0009034-32-6** hemicellulose

The following additives are used in the formulation

No information given		

The following metals are listed as present in the material:

No information given

The composition of the end product is not public. The producer owns this information and wants to keep it confidential. Due to the fact that the end product in not yet in production, no specified product DOC is available.

Which risks strategies are applied?

The producer of the patented bio-polymer has a focus on the quality of the raw material. It is biomaterial and during harvesting there are all kinds of risks and dependencies caused by location, weather and season influences. Requirements are therefore set for, among other things, water content, sugar content, hygiene, the use of pesticides and the general condition of the leaves. Selection is therefore made at the front, so that the risks in the follow-up process are minimized. Another strategy to prevent risk and to ensure the quality of the end product is the fact that products made of the patented material can only be produced under license.

The license agreements stipulate that specific conditions must be met when using the patented bio-plastic and that, among other things, the end product must be 100% bio-based and 100% home compostable. This therefore also applies to all ingredients and auxiliaries to be used. In addition, all substances must be on the positive list for use as FCM and the end product must comply with (EU) legislation. The producer must demonstrate compliance with the relevant migration tests. If necessary, research support is given to the developers and producers.

The IRGC framework is unknown, none of the people interviewed in the life cycle of this product knew the institution or model

Which motivations and barriers in the applied risk strategy are experienced?

The ambition of the company is to use worldwide available agricultural waste material and transforming it via a low cost & low tech process into a generic (home)biodegradable polymer, that can be used by any injection moulder or extruder on existing standard equipment and tools. By involving local farmers in the process and also in developing the production facilities close to the harvest sites, the local economy is stimulated. Another goal is to produce CO2 neutral, by introducing a tree planting program to compensate all the emissions produced by harvesting, production and transport.

The applied risk strategy aims to ensure that the end product is sustainable and that the quality is guaranteed. The strategy must also ensure that end product complies with regulations.

The producer mentioned the bureaucracy of research as a real barrier. Everything runs through protocols. If you market a unique product with unique features, you must be able to deviate from the standard protocols. For example, tests that must be carried out at a high temperature according to protocol cannot be done with this product without the sugars burning. This does not mean that the product is not suitable and not safe, within the proper use! Also the confidentiality of the product data was mentioned as a barrier. Agreements had to be made with all involved parties. Because of this the applied risk strategy is very internally controlled and not transparent.

Where is the responsibility placed?

The producer of the patented biopolymer act as a supplier of one of the raw materials.
He is, like all other suppliers, responsible for the quality and safety of his product.
Special in this case is that his product may only be used under license. Therefore the producer of the end product must meet specific conditions to ensure that the end product is 100% bio-based and biodegradable.

The licensor wants to formally monitor the entire chain. As already stated, the suppliers and the producers are expected to demonstrate that the risks are controlled and that the producs comply to regulations. In addition, only safe certified raw materials are used and certified producers are involved. In principle, our risk assessment and the responsibilties are based on the license agreements.

The responsibility for the waste phase is placed with the consumer and the waste processor.

Comparison with the IRGC Risk Governance framework

The comparison results are shown in the table below.

IRGC RG framework subject	**Producer's statements**	**Comparative judgement**
Pre-assessment (orientation)		
Are the risks as well as the opportunities that are addressed with the introduction of this new FCM known?	Yes, I think we have a clear picture of the possible risks, such as the use of plant protection products. That is why we apply gate control. With regard to the possibilities, it seems obvious that we are contributing to a sustainable packaging industry. With this product we try to keep the environmental burden as low as possible, we become less dependent on fossil raw materials and we	Meets basic principles

	contribute to a circular economy. An important principle for us is that we do not leave micro-plastics behind with our products. Due to the 100% home compostability requirement, we can meet this.	
Are stakeholders views and their affection (emotion) to the definition and framing of the risks and opportunities used?	Through a license agreement you guarantee the input of all partners in the chain. These are therefore seen as the stakeholders. The company is aware of the image and framing of compostable bio-based plastic products.	Meets partially: not all stakeholders in the life circle are involved.
Are foresight or horizon scanning techniques for the identification of emerging risks used?	No.	Does not meet
Are multidisciplinary experts involved in the risk identification?	no, not specifically as part of the risk assessment process. We do, however, use research institutes. We work with high-quality laboratories and scientists through our partners in India. If we have specific questions about the presence / absence of substances, or if we want to have insight into processes or for specific migration tests, we have India investigated. If necessary for EU legislation, for example, we use standard institutions such as TNO, SGS and the like	Does not meet
Have different dimensions been assigned to the identified risks?	We do not deal structurally with risks, no identification, classification and evaluation	Does not meet
Were there boundaries set in the assessment and evaluation, in terms of scope, scale or time horizon?	As a licensor, we want to formally monitor the entire chain. It is our mission and vision that our product is only used for safe and sustainable products. We look ahead and look for new usage applications. For example, we are also working on improving the "after use" phase. Is it possible to re-use the product? What possible disadvantages and potential risks of the product should we then eliminate?	Meets partially: Limited scope
Risk appraisal (taxation)		
Are the possible consequences of the identified risks estimated?	No. Because we do not really do a risk identification of the end product, this question cannot be answered.	Does not meet
Is it known which processes create and control the risks?	Yes, the risks that we have identified are part of our raw material. - Presence of residues of plant protection products. - Presence of other toxic substances (biotoxins or environmental contaminants) - Wrong composition. - General condition of the leaves By selecting this at the gate, we believe that in principle we have covered all risks.	Meets basic principles
Are the identified risks quantified?	Yes, we have established minimum requirements that must be met. It is right or wrong.	Meets basic principles
Are (worse case) scenarios considered in the risk appraisal?	No	Does not meet
How are uncertainties dealt with during the assessment?	Not done.	Does not meet
Are the different stakeholders' opinions, values and concerns about the risk known and used? What is their level of involvement, accountability or responsibility?	As a company, we involve all links in the chain from raw material to end product to deliver a beautiful product together. We do this through a license construction. Hereby we try to properly identify the wishes and responsibilities and we take into account the (im) possibilities to come to a safe and	Meets partially: not all stakeholders in the life circle are involved.

	sustainable product. This is therefore mainly internally focused.	
Are cognitive or heuristic biases that affect the risk perception or concern investigated?	No, not specifically, we try to make a marketable, safe and sustainable product together with all players in the chain, in which we discuss and communicate risks.	Meets partially: not all stakeholders in the life circle are involved.
Are sociological, organisational and anthropological constraints identified on actors and stakeholders?	We are certainly aware of cultural differences and socio-economic circumstances for each stakeholder. That is why we also want to be a community in which we work together to ensure sustainable products and locally better economic conditions without damaging the local environment. If we live up to this, there will be little to no resistance.	Meets basic principles
Is the producer prepared to face controversies and conflicts due to differences in risk perception, in stakeholder objectives and values, or from inequities in the distribution of benefits and risks?	Yes, we do keep a close eye on the social debate about the use of plastic. We are aware of the social discussions and I actively contribute to this discussion by bringing the facts and myths surrounding bio-plastics to the attention of consumers and politicians wherever possible.	Meets basic principles
Characterisation and evaluation (making choices)		
Are the identified risks characterised in terms of complexity, uncertainty and ambiguity?	No, as already mentioned, our risk analysis is of a different nature. We only use entry requirements for our raw material. So we do not deal with risks on a structural basis, not identification, classification and evaluation	Does not meet
Are there criteria for acceptability, tolerability or intolerability?	No	Does not meet
What are the societal values and norms for making judgments about tolerability and acceptability? Are these values and norms changing?	Our mission and vision make clear what we stand for: the development and production of consumer and consumer articles that have a minimal impact on the environment and minimize the use of fossil raw materials. In addition, we demand that our partners respect human rights (including prevention of child labor and good working conditions) and stimulate the local economy without burdening the local environment. We strive for the highest possible level of sustainability.	Meets basic principles
Are there constraints involved in the judgement (e.g. time, budget, context, etc.)?	Yes, money and time are important. It must fit in with the business plan. We invest in development, but our business model is ultimately selling sustainable products. But we make no concessions with regard to 100% biobased and 100% home compostable	No Judgement, informative
How does decision-making come about? Who's in the lead?	The decisions are made by the management. Together with the chain partners, products are developed and it is examined whether there is a market for it. Of course, the product must also be safe, but market exploration and responding to market wishes determine the choice in the first instance.	No Judgement, informative. Remark: Stakeholders have no vote.
If there is a possibility of substitution? How are risks compared? With aspects weight heavier?	When developing products, we naturally look at various options for composition and method of production, comparing properties, costs and potential risks. Costumer requirements and complying with legislation are the most important, then of course the costs and availability of the raw materials and production lines.	Meets partially: Limited scope, food safety and environmental burden is not mentioned

Management (control)		
How is the management organized of the identified risks?	In view of our activities, we largely place the responsibility for managing the risks with the partners. We ask them to guarantee safe products. Our risk assessment consists of demanding guarantees in the form of certificates and statements. In addition, we carry out verification investigations of the end product to test whether the composition is still original. This method is part of the licensing agreements and our partners have no problems with this	Meets partially: Limited scope
How to choose between the various management options (e.g. technological, regulatory, institutional, educational, transfer, compensation, etc.)?	We do not really choose our management options based on identified risks. We provide a raw material which, in our opinion, does not require any risk management. Where there are potential risks, we tackle them at the source.	Meets partially: Limited scope
Are international cooperation and harmonisation for global, trans-boundary or systemic risks taken in to account in the decision process?	Yes, we work together with international partners and are active to strengthen the sector internationally and to tackle potential risks together.	Meets basic principles
Are all options evaluated and prioritised? Are potential trade-offs between risks, benefits and risk-reduction measures that may arise, considered?	No, not structural. In development, this will certainly be applied, but not to a predefined method. It is applied in a broader context within the chain, for example by searching together for alternatives for the transport of the raw material and the location for the production facility for our polymer.	Meets partially: Not structural
How are the management decision and actions effectivity in the long term assured?	Here, too, we do not look at the risks structurally, but naturally we respond to new insights and potential risks that our polymer can entail in products. We do this primarily through our scientific research partner in India, where we can submit all research questions relatively easily and cheaply.	Meets partially: Not structural
Cross cutting aspects (stakeholder involvement)		
How is ensured that the communication process is organized in a way that two-way information is effective, enlightening and timely?	As a team we promote our products, if there are specific questions, we try to answer them through our experts. We do not really have a communication procedure, we arrange this ad hoc within our small team.	Meets partially: Limited scopel
Are the demands, needs and purposes for information and communication among the different stakeholder groups, including members of the general public known?	Think so, as we have already indicated, we are open to this. If there are any questions about our products we try to answer them as well as possible.	Meets basic principles
Is there a protocol: How to deal with ambiguities and controversies about the risk within the public sphere?	No	Does not meet
How is confidential and sensitive information dealt with?	This does not play a role in risk communication, of course we respect the person and / or company confidentiality and sensitivities. We will also respect the privacy legislation, but we will be open about the possible risks if this were to happen with our products.	Meets basic principles
Are the media used for risk communication and increasing the stakeholders involvement, both traditional and social?	Yes, we use all kind of media.	Meets basic principles

Appendix III

Detailed results of the chemical analyses

The investigation consisted of screening for the presence of Non-intentionally added substances (NIAS) and an analysis for the presence of metals in the sampled materials. The chemical analyses were performed at the NVWA laboratory for product safety, located at Paterswoldseweg 1, 9726 BA Groningen.

18 different bio-based plastic FCMs available on the Dutch market were randomly sampled, see table III.1 for an overview. The samples are listen in 3 groups, based on their main content. Group 1: (c)PLA, group 2: Cellulose fibre compound and group 3: Combinations.

Table III.1. *Overview of sampled FCMs*

Sample description	Appearance	Main content	Compostable claim
Group 1. PLA			
Bowl (tableware)	Transparent plastic	Polylactid acid	?, not available.
Spoon	White plastic	Polylactid acid	Compostable
Cup (tableware)	Transparent plastic	Polylactid acid	Compostable
Container for meat	Transparent plastic	Polylactid acid	Compostable
Container for meat	Green plastic	Polylactid acid	Compostable
Cold drinks cups	Transparent plastic	Polylactid acid	?, not available.
Coffee cup	White plastic	Polylactid acid	?, not available.
Packaging film	Printed plastic	Polylactid acid	Compostable
Packaging film	Printed plastic	Polylactid acid	Compostable
Cup (tableware)	Brown paper	Polylactid acid	Compostable
Group 2. Cellulose fibre compound			
Snack tray	Brown cardboard	Cellulose fibre compound	Compostable
Plate (tableware)	White cardboard	Cellulose fibre compound	?, not available.
Plate (tableware)	White cardboard	Cellulose fibre compound	?, not available.
Tray (tableware)	Beige cardboard	Cellulose fibre compound	Compostable
Fork	Naturally woody	Cellulose fibre compound	?, not available.
Group 3. Combinations			
Bread bags	Brown paper with transparent plastic	Cellulose fibre compound and polylactid acid.	?, not available.
Tray (tableware)	Inside white, outside brown cardboard	Cellulose fibre compound and polylactid acid.	Compostable
Tray (tableware)	Naturally woody	Inside cellulose fibre compound, outside Kantstik Q powder (lubricant)	?, not available.

Methods

Description of the applied method for screening for NIAS with GC-MS:

The preparation of the samples was done in the following manner: Cut a portion of the material into small pieces. Weigh approximately 300 mg in a glass tube. Add 1.5 ml acetone followed by 100 µl IS solution of 10 µg /ml dodecane in hexane. Ultrasonic treatment for 30 minutes, filtering and transferring in a vial. 1µl of the prepared sample was under split less conditions injected into a gas chromatographic system (Agilent Technologies 7890B) and analysed with mass selective detection (Agilent Technologies 5977A). The mass range was set with a start limit of 29, the end limit was 450, a threshold of 150 was used. The chromatogram was investigated for available components by comparing the spectra with library spectra. The method used for the GC-MS analysis is described in the NVWA standard operation procedure CHE01-ND816 v7: *Identification and quantification of components in different matrices using GC-MS* (NVWA, 2016).

Description of the applied method for the analysis of the presence of metals with ICP-MS:

The preparation of the samples was done by destruction of 0.1 gram in 5 ml of HNO3 and 1 ml of H2O2 and 2 ml of double distilled water using a microwave. 4 ml of a prepared sample was analysed using Inductively Coupled Plasma in combination with mass selective detection (MSD) system (Perkin Elmer Nexion 2000). Step 1: in 4 minutes from 20 ℃ to 200 ℃. Step 2: 8 minutes at 200 ℃. The method used for the ICP-MS analysis is described in the NVWA standard operation procedure CHE01-WV408 v5: *Determination of elements in simulant after migration from articles intended to come in contact with food using ICP-MS* (NVWA, 2018).

In Table III.2 an, in random order, qualitative overview is given of the detected substances and metals per sample.

Important notes:

Only a screening has been performed, the identified substances are not confirmed. Therefore the results must be qualified as **indicative.**

The results are **qualitative,** the presence of the substances has been demonstrated, the concentration of the substance in the samples has not been determined.

Table III.2 Overview identified substances and metals detected		+ =																	
		Samples in random order:																	
Name*	**CAS nr.**	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	1	2	3
Substance																			
Melkzuur (mono- en/of dimeren)	50-21-5/ 79-33-4	+		+	+		+	+		+									
Palmitinezuur	57-10-3				+	+				+		+		+	+	+	+	+	+
Laurinezuur	143-07-7				+					+									
Mysterinezuur	544-63-8	+		+				+				+		+	+		+	+	+
Stearinezuur	57-11-4	+	+	+	+		+	+		+		+	+	+	+	+	+	+	
Butylcitraat	77-94-1			+															
dipropyleenglycol	110-98-5											+							
pentadecaanzuur	1002-84-2											+							+
elaidinezuur	112-79-8											+			+		+		
2,4,7,9-tetramethyldec-5-yne-4,7-diol	126-86-3																+		
Isopimarinezuur	5835-26-7																+		
Veratraldehyde	5973-71-7/ 5779-95-3	+																+	
dimethyl benzoezuur	499-06-9/ 619-04-5	+																	
propyleenglycol	57-55-6													+	+				
pentadecaanzuur	1002-84-2																	+	
didodecylthiodipropionaat	123-28-4						+												
vanilline	121-33-5					+										+			+
p-hydroxybenzoëzuur	99-96-7																		+
hexahydrofarnesyl acetone	502-69-2																		+
diverse vetzuren, stearinezuur	112-79-8/ 57-11-4/ 506-12-7					+								+				+	+
glycerine	56-81-5								+		+					+			
ureum	57-13-6								+		+								
N-ethyl-p-tolueensulfonamide	80-39-7								+		+								
acetyltributylcitraat	77-90-7								+		+								
hydroxydihydromaltol	28564-83-2															+			
5-Hydroxymethylfurfural	67-47-0															+			
4-hydroxybenzaldehyde	123-08-0					+										+			
2,6-Dimethoxy-1,4-benzoquinone	530-55-2															+			
4-cumaarzuur	7400-08-0															+			
dimethoxyhydroxycinnamalde	7345-53-7															+			
linolzuur	60-33-3															+			
oleamide	75-11-4					+										+			
stigmasterol	83-48-7					+									+	+			+
sitosterol	83-47-6					+									+	+			+
campesterol	474-48-7														+	+			
fytol	150-86-7														+				

Name*	CAS nr	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Dodecyl acrylaat	2156-97-0														+				
Didodecyl 3,3'-thiodipropionaat	123-28-4		+																
p-Tolualdehyde	104-87-0												+						
Octamethylcyclotetrasiloxane	556-67-2				+					+									
1-chloordodecaan	112-52-7				+														
1-chloortetradecaan	2425-54-9				+														
1-chloorhexadecaan	4860-03-1				+														
Metals																			
Li			+	+				+				+		+	+			+	
B								+	+		+			+	+			+	+
Al		+	+		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
V			+					+						+	+			+	
Cr			+					+				+	+	+	+		+	+	
Mn			+		+	+		+	+		+	+	+	+	+	+	+	+	+
Fe		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Co								+											
Ni			+					+	+		+	+		+	+			+	
Cu					+	+		+	+		+	+		+	+	+	+	+	+
Zn		+	+	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+
Ge								+											
As						+		+											
Se							+	+	+			+					+	+	
Rb								+								+		+	+
Sr			+			+	+	+	+		+	+	+	+	+	+	+	+	+
Zr			+		+	+		+	+		+	+							
Mo								+											
Pd																			
Cd		+	+	+		+	+	+	+		+	+	+	+	+	+	+	+	+
Sb														+	+			+	
Ba			+			+	+	+	+		+	+	+	+	+	+	+	+	+
Ce			+					+						+	+		+	+	
Hf								+				+		+					
Hg			+			+	+	+	+		+	+	+	+	+	+	+	+	+
Pb			+			+		+					+	+	+			+	
Bi																			

*= in Dutch

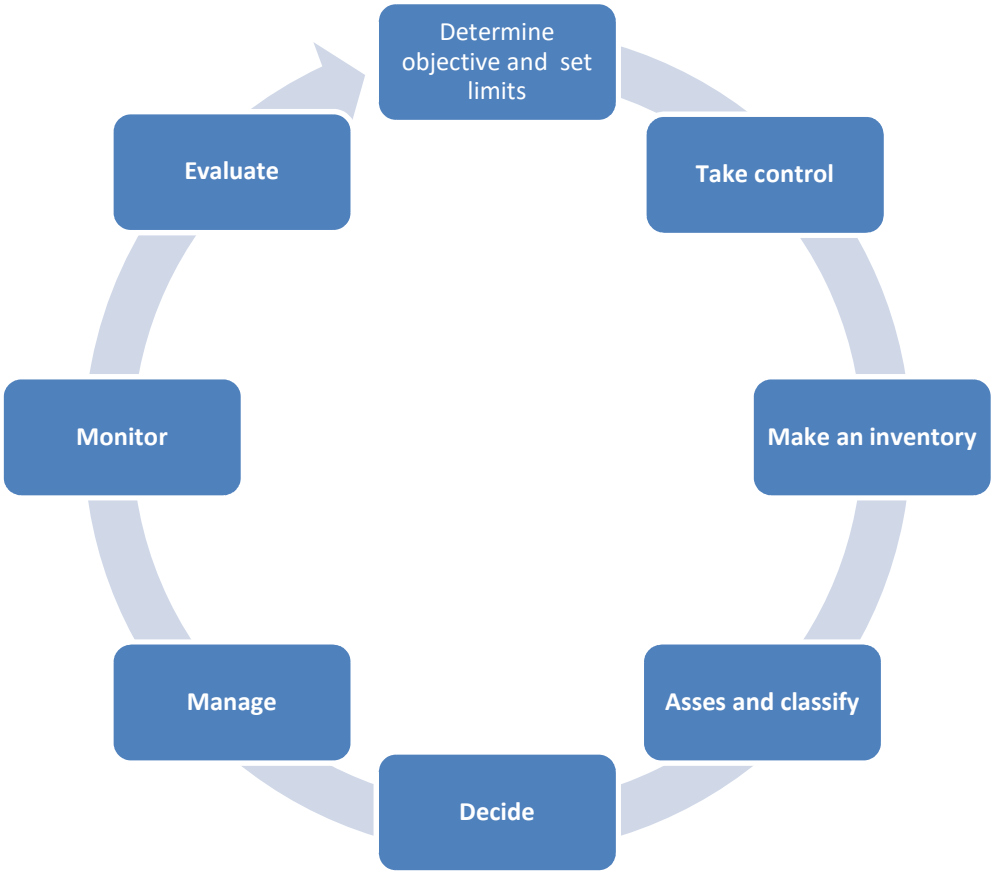
Appendix IV

Example of a relatively simple risk governance framework and some best practice examples of risk strategies.

Relatively simple risk governance framework

This example is based on the principle of the Plan-Do-Check-Act management method (Maruta, 2012; Moen & Norman, 2010) and the 4 steps and the 3 cross cutting aspects from the IRGC framework (IRGC, 2017).

Schematically presentation:



Description of the different parts:

1. Determine objective and set limits
Determine in advance how risks should be assessed and which criteria should be applied.
What is still acceptable, what are the limits?

2. Take Control
Describe the risk governance procedure in a protocol and make it part of the management system. Build a file in which all information can be found and use standard templates for compiling file per risk (risk matrix). Appoint a risk "manager" who is responsible for the execution of the process and the management of the file.

3. Make an inventory
Make an inventory as broad as possible. Make an overview of all possible risks**.**
The following principles will have to be implemented to a greater or lesser extent, depending on the possibilities of the company and the complexity of the subject.

- Be open and honest about the raw materials, the formula, the technique, the production, the composition, the properties and the applications of the end product.
- Inform as broadly as possible. Do this not only internally, with a small select group. The more stakeholders from the entire chain from raw material suppliers to waste processors are involved, the better.
- Multidisciplinary approach, ask various scientists / experts from different disciplines to think and discuss about the possible risks.
- Consider the entire life cycle of the product.
- Assume worst case scenarios, abuse and unintended applications.
- Take into account short and long-term effects, regardless of place and time.
- Involve social and political aspects, not only in the Netherlands but worldwide.

4. Asses and classify
Assess and classify each identified risk by:
- Probability
- Complexity
- Uncertainty
- Impact
- Manageability

5. Decide
Decide on the progress by answering the following questions:
- Which risks are acceptable and which risks are not.
- Do we still want to market the product?
- Do we have to make changes to the design?
- Are there alternatives?
- How are we going to reduce or manage acceptable risks?
- How do we communicate about the potential risks of the product?

6. Manage
Identify the critical points per risk and determine the acceptable limits for these point.
Make a management plan that is accepted and supported by all stakeholders.

7. Monitor
Follow the product, how is it used, how stable / robust is it.
Check if the known risks are controlled and if the measures taken are effective?

8.Evaluate
Evaluate all activities done within the framework. Investigate whether risks have changed in classification or whether there are indications of potential new risks, .
Use the results from the monitoring, new (scientific) insights, change within legislation and changing social discussions and acceptances.

Use the finding of the evaluation as new input for the cycle.

Some best practice examples of risk strategies.

Only use raw materials and additives with a complete, reliable and representative analysis certificate.

Provide a current and complete file in which all information can be found.

Implement internal insurance procedures and clear process instruction for the staff.

Perform a complete analysis of the end product with the appropriate methods. Asses all substances found on their properties and the possible risks that can occur.

Involve all relevant stakeholders of the life cycle of the end product in the risk management plan.

Organize regular consultations with stakeholders and experts about the experiences with the end product over time.

An essential part of good risk governance is informing the society and in particular the consumer about the advantages and disadvantages of the product. This allows society to determine for itself which risks are acceptable and how they should / would like to deal with them.

During the workshop, the experiment of working in groups with different expertise turned out to be very effective for identifying potential risks and coming up with possible measures to control them. It is recommended to structurally organize these kinds of meetings as input for the evaluation of the risks associated with the development and use of new sustainable materials

Appendix V

List of participants

	Interview	Workshop	Limited communication
Dr. Ir. D. (Dirk) van Aken		X	
Ir. G.C. (Geert) Bergsma	X		
Ir. H. (Hendrik) Bom	X		
Dr. Ir. K. (Krista) Bouma	X	X	
Ing. T. (Tim) Brethouwer	X	X	
Ir. R. (Rob) van der Bruggen	X		
Ing. C.A. (Caroli) Buitenhuis			X
Dr. D.S. (Daan) van Es	X		
Dr. Ir. L. (Lily) Fredrix		X	
Ing. P. (Patrick) Gerritsen	X		
Ir. N.A.M.(Nikki) Groote Schaarsberg	X	X	
Ir. F.J. (Fred) Hakkenbroek	X		
Drs. A.K. (Toon) van Harmelen	X	X	
Drs. A. (Ady) Jager		X	
O. (Olaf) Janmaat		X	
Ing. M. (Marco) Jansen			X
E. (Elwin) Kersten			X
Ir. M.(Mark) Lepelaar	X		
Ir. K. (Karin) Molenveld	X		
P. (Patrice) Punt MSc.		X	
Ir. H. (Hidde) Rang	X	X	
Prof. Dr. T.H.M. (Dick) Sijm		X	
Ir. H. (Henk) Vooijs		X	
Dr. Sicco de Vos	X		